OFFERING CARE TO OLDER COMMUNITY-DWELLING WOMEN WITH URINARY INCONTINENCE

Els Visser

The study described in this thesis was financially supported by:

Publication of this thesis was financially supported by:

Offering care to older community-dwelling women with urinary incontinence.

ISBN	978-90-367-7143-6 (printed version)
ISBN	978-90-367-7144-3 (electronic version)
Cover design	Linda van Zijp, StudioLin.nl, Rotterdam, The Netherlands
Printed by	Ridderprint, Ridderkerk, The Netherlands

rijksuniversiteit
groningen

Offering care to older community-dwelling women with urinary incontinence

Proefschrift

ter verkrijging van de graad van doctor aan de
Rijksuniversiteit Groningen
op gezag van de
rector magnificus, prof. dr. E. Sterken,
en volgens besluit van het College voor Promoties.

De openbare verdediging zal plaatsvinden op

woensdag 24 september 2014 om 16.15 uur

door

Els Visser

geboren op 19 november 1982
te Leiden

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CHAPTER 1

General introduction

The main focus of this thesis is to investigate the effects and cost-effectiveness of offering diagnostic testing and tailored treatment to older community-dwelling women with urinary incontinence as compared to usual care, in a population that did not seek help on their own initiative. This was explored in a cluster randomized controlled trial: the URinary INcontinence in Older women (URINO) trial. This chapter provides background information about urinary incontinence, as well as an overview of the objectives of the thesis, a summary of the methods used in the URINO trial, and a general outline of the thesis.

BACKGROUND

Urinary incontinence in women

According to the International Continence Society (ICS), urinary incontinence is defined as the complaint of involuntary loss of urine[1]. Basically, urinary incontinence can be divided into three main subtypes: stress urinary incontinence (complaint of involuntary loss of urine on effort of physical exertion, or on sneezing or coughing), urgency urinary incontinence (complaint of involuntary loss of urine associated with urgency) and mixed urinary incontinence (where stress and urgency symptoms coexist). Other subtypes, like postural urinary incontinence, nocturnal enuresis, insensible urinary incontinence or continuous urinary incontinence (formerly known as overflow urinary incontinence), are less frequent.

In women, urinary incontinence is very common and its prevalence considerably increases with age: in community-dwelling women aged over 55 years, the prevalence increases from 28% at age 55-59 years to 40% in women ≥ 80 years[2]. The severity of the symptoms, expressed as a combination of frequency and amount of urine loss, also increases when patients get older[3]. In the younger age categories, stress urinary incontinence is the predominant type (51% experiences stress urinary incontinence, 31% mixed and 14% urgency) whereas from age 55 years onwards there is a shift to predominantly mixed urinary incontinence symptoms (42% suffer from mixed symptoms, 32% from stress and 19% from urgency)[2].

Continence and micturition require optimal coordination between urethral closure mechanisms and detrusor muscle activity. The pelvic floor plays an important role in this balanced system. It is composed of fibres of the coccygeus, levator ani, urethral and sphincter muscles, and connective tissue attachments to the bony pelvis (Figure 1). Dysfunction of the pelvic floor, with either hypertonic or hypotonic muscles, or a damaged pelvic floor caused by childbirth, may result in urinary incontinence.

Risk factors for urinary incontinence are higher age, parity, hormonal replacement therapy, obesity, diabetes, urinary tract infections, depression, smoking, chronic lung

disease, a family history of incontinence, and genitourinary problems such as pelvic organ prolapse, or having had urogynaecological surgery[4].

Urinary incontinence in older women

In older women, urinary incontinence is a complex disorder as it involves multiple interacting risk factors, including age-related changes and comorbidity[5]. In addition, impaired physical functioning and restricted mobility may contribute to urinary incontinence in this population, since continence requires an intact functional ability to toilet oneself[4]. Also important are age-related physiological changes, such as an increase in the number of involuntary detrusor contractions, a decrease in the detrusor contractility, a decrease in urethral closure pressure, and low oestrogen levels resulting in atrophy of the superficial and intermediate layers of the urethral mucosal epithelium; all these may result in urinary incontinence[6].

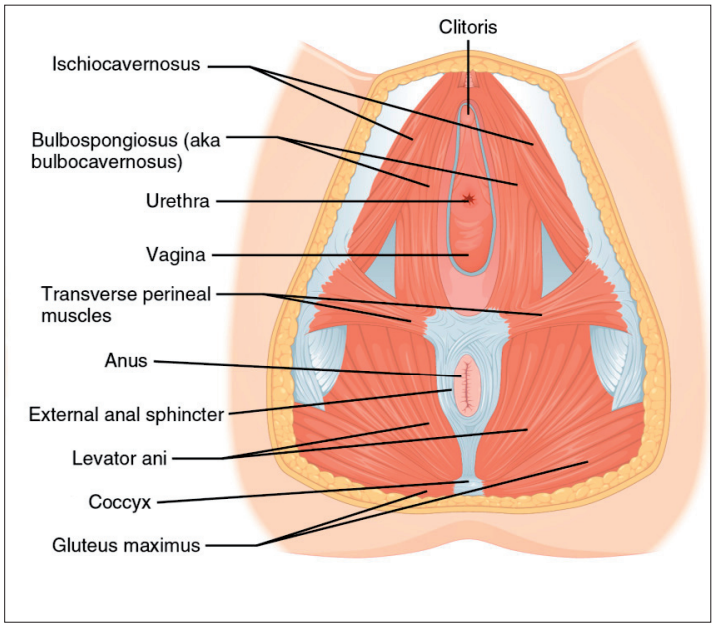

Figure 1 Inferior view of the female pelvic floor[7].

Impact on quality of life and sexual functioning

Although urinary incontinence is not a life-threatening disease, the consequences of this condition on quality of life may be considerable. The condition often causes embarrassment, stress, frustration, loss of sense of dignity, depressive feelings, and limitations in activities because of (fear of) involuntary loss of urine[8, 9]. There is no consensus in the medical literature as to what type of urinary incontinence has the

most negative influence on quality of life, or regarding what role the severity of symptoms plays in terms of impact on quality of life. However, most studies report that patients with severe symptoms of mixed or urgency urinary incontinence, and patients in whom urine loss interferes with sexual activities, experience the greatest impact on their quality of life[4].

Urinary incontinence may also have a negative impact on sexual well-being and there is increasing evidence that treatment of urinary incontinence may indeed improve sexual function[10, 11]. However, knowledge on the sexual health of older community-dwelling patients with urinary incontinence is still scarce.

Diagnosis and treatment of urinary incontinence in general practice

In the Netherlands, the guideline of the Dutch College of General Practitioners (NHG) summarizes the evidence and gives recommendations for the diagnosis and treatment of urinary incontinence in general practice[12]. This guideline advises the general practitioner to take a clinical history and to perform a physical examination in a patient who consults her doctor for urinary incontinence. The clinical history is aimed at identifying the predominant type of urinary incontinence, as well as assessing the severity and impact of the symptoms[13]. Also, the physician should ascertain whether there is an underlying condition contributing to the involuntary loss of urine. The physical examination consists of an examination of the abdomen and a bimanual vaginal palpation. Urine should be analysed to exclude urinary tract infections. Patients in whom the type of urinary incontinence cannot be ascertained are asked to fill in a three-day bladder diary. A bladder diary is a record of liquid intake, urine output and incontinence episodes; by evaluating fluid balance, urinary frequency and functional bladder capacity, the general practitioner is able to establish urgency symptoms such as polyuria.

Because of the lack of evidence on the additional value, and the high accuracy of the clinical history in diagnosing the type of urinary incontinence as compared to urodynamic testing, performing urodynamic testing in primary care prior to treatment is currently not recommended[13, 14]. Evidence for the predictive value of the clinical history in patients aged ≥ 65 years is also lacking. It is also unclear what the additional value of the cough stress test (here, patients with a naturally filled bladder are asked to cough in standing and supine position; used to diagnose stress urinary incontinence) is with respect to the diagnosis of urinary incontinence. Therefore, also this test is currently not recommended[15].

Most women with urinary incontinence can be correctly diagnosed in general practice[15]. So after the diagnostic process, the general practitioner is usually able to start treatment. Several non-invasive effective treatments are available, also for older women[16]. The Dutch guideline indicates that pelvic floor exercises are the preferred

first-line treatment for patients with predominantly symptoms of stress urinary incontinence, and bladder training for urgency symptoms[17, 18]. In case of stress urinary incontinence, the general practitioner may instruct patients about pelvic floor exercises, or refer them to a pelvic physiotherapist when patients have difficulty with contracting their pelvic floor muscles. If a patient is diagnosed with urgency urinary incontinence the micturition pattern needs to be corrected by bladder training: the general practitioner is advised to instruct the patient to gradually delay micturition when they feel urgency. When this is not effective, anticholinergic drug prescription can be considered[19]. In addition, there are indications that pelvic floor physiotherapy is also effective in urgency urinary incontinence[20]. Patients with mixed urinary incontinence are first treated for the symptoms (either stress or urgency symptoms) that bother them the most. Referral to a secondary care specialist is recommended when the diagnosis is unclear, when there is a severe pelvic organ prolapse, continuous urinary incontinence (e.g. when there is retention of urine), a malignancy, or when conservative treatment has failed.

Underuse of effective treatment options

Despite the negative impact of urinary incontinence on quality of life and the availability of effective treatment options, help-seeking for urinary incontinence in older women remains limited. The prevalence of urinary incontinence in general practice is considerably lower than in the open population; only 3.9% of the women registered in a general practice are registered with urinary incontinence, while 28 to 40% of the women in the open population are known to have urinary incontinence[2, 12]. Moreover, only 30 to 50% of the affected older women seek help for their symptoms[21]. The main reasons for this are that patients feel ashamed, or they believe that urinary incontinence is a natural consequence of ageing, or they think that no treatment options are available[22-25]. This leaves many older incontinent patients with unresolved physical, functional and psychological problems, and a diminished quality of life, both at home and at work[26]. It is unclear whether these women who hesitate to seek help have specific characteristics. Knowledge on such characteristics might be valuable, since these women might profit from a proactive approach from a healthcare professional who invites them to undergo diagnostic testing and treatment. Moreover, it is uncertain whether these women would even accept such an invitation and whether they will benefit from treatment; women who do visit a healthcare professional are known to benefit from such a visit.

Besides the patient-related factors that may interfere with good management of urinary incontinence in older women, also factors related to the general practitioner may play a role, e.g. therapeutic nihilism, not feeling confident to manage urinary incontinence, lack of time, and lack of knowledge on the available therapeutic options

and their effectiveness[22]. Due to these potential problems, and also to the multi-causality of urinary incontinence in older women, the treatment pathway for these women is not always clear[5]. Compared with younger women, older women are more frequently inadequately treated and prescribed incontinence pads, instead of pelvic floor exercises and bladder training, or referred to secondary care[27, 28]. Therefore, most older patients using incontinence pads experience suboptimal care from their general practitioner[29].

Costs

Because help-seeking in the elderly is limited, often due to both patient-related and physician-related factors, effective treatment options are underused and many older women cope with their incontinence symptoms by using absorbent products[22, 28]. This implies that urinary incontinence in older women is not only a condition with a high disease burden, but also a rather costly disease. In the Netherlands, in 2012 more than 163 million euros were spent on incontinence products[30]. As urinary incontinence generally worsens over time, the number of incontinence pads used in a lifetime and the related costs are high[16].

OBJECTIVES OF THE THESIS

The main objective of the study described in this thesis was to evaluate the effects and cost-effectiveness of offering older community-dwelling women with urinary incontinence diagnostic testing and tailored treatment, as compared to standard care according to the guidelines of the Dutch College of General Practitioners, in a population that did not seek help on their own initiative[12].

In addition, this study offered the opportunity to investigate i) whether urinary incontinence is a condition that fulfills the international criteria for responsible and acceptable screening , ii) which women hesitate to seek help and might profit from screening, iii) which type of urinary incontinence has the most negative influence on quality of life and what role the severity of the symptoms plays in terms of impact on quality of life, and iv) the impact of urinary incontinence on sexual functioning of older community-dwelling women.

THE URINO TRIAL

The URINO trial was conducted to examine the effects and cost-effectiveness of offering diagnostic testing and tailored treatment to older community-dwelling women

with urinary incontinence who did not seek help on their own initiative. It is a cluster randomized controlled trial in which general practitioners were randomized instead of patients, in order to avoid contamination.

Community-dwelling women aged 55 years and older were proactively approached by means of a postal screening questionnaire (Figure 2). Women positively screened for urinary incontinence were invited to participate.

Patients in the intervention group were invited to undergo a protocolized physical examination. Subsequently, they received a treatment advice. Since urinary incontinence in older women is a multifactorial problem, this treatment advice was formulated by a multidisciplinary expert team.

Patients in the control group received usual care, meaning that they were only physically examined and treated according to the guidelines of the Dutch College of General Practitioners when they decided to visit their general practitioner[12].

At the 12-months follow-up, the effect of the intervention on severity of symptoms, the number of incontinent episodes per day, disease-specific and generic quality of life, as well as costs, were evaluated.

The hypothesis was that diagnosing and treating older community-dwelling patients with urinary incontinence who did not seek help on their own initiative would have a positive effect on the clinical parameters against acceptable costs.

OUTLINE OF THE THESIS

Chapter 2 outlines the design of the URINO trial , presents the results of the effect of screening on treatment uptake, and discusses whether urinary incontinence is an appropriate condition to screen in view of the 10 criteria for responsible and acceptable screening as formulated by Wilson and Jungner[31]. *Chapter 3* describes the clinical effects of the URINO trial. In *chapter 4*, the cost-effectiveness of the trial is reported in a cost-effectiveness analysis and cost-utility analysis. *Chapter 5* describes which women might profit from screening for urinary incontinence by analyzing the characteristics of the women who hesitate to seek help. The study in *chapter 6* explores whether the three main types of urinary incontinence differ with regard to their effects on generic and disease-specific quality of life, and whether the severity or type of incontinence influences the person's quality of life. *Chapter 7* describes the impact of urinary incontinence on sexual functioning in older community-dwelling women. The sexual problems of sexually active patients are reported, and the reasons for not being sexually active and the predictors of sexual activity are described. *Chapter 8* summarises the results, presents conclusions, discusses methodological

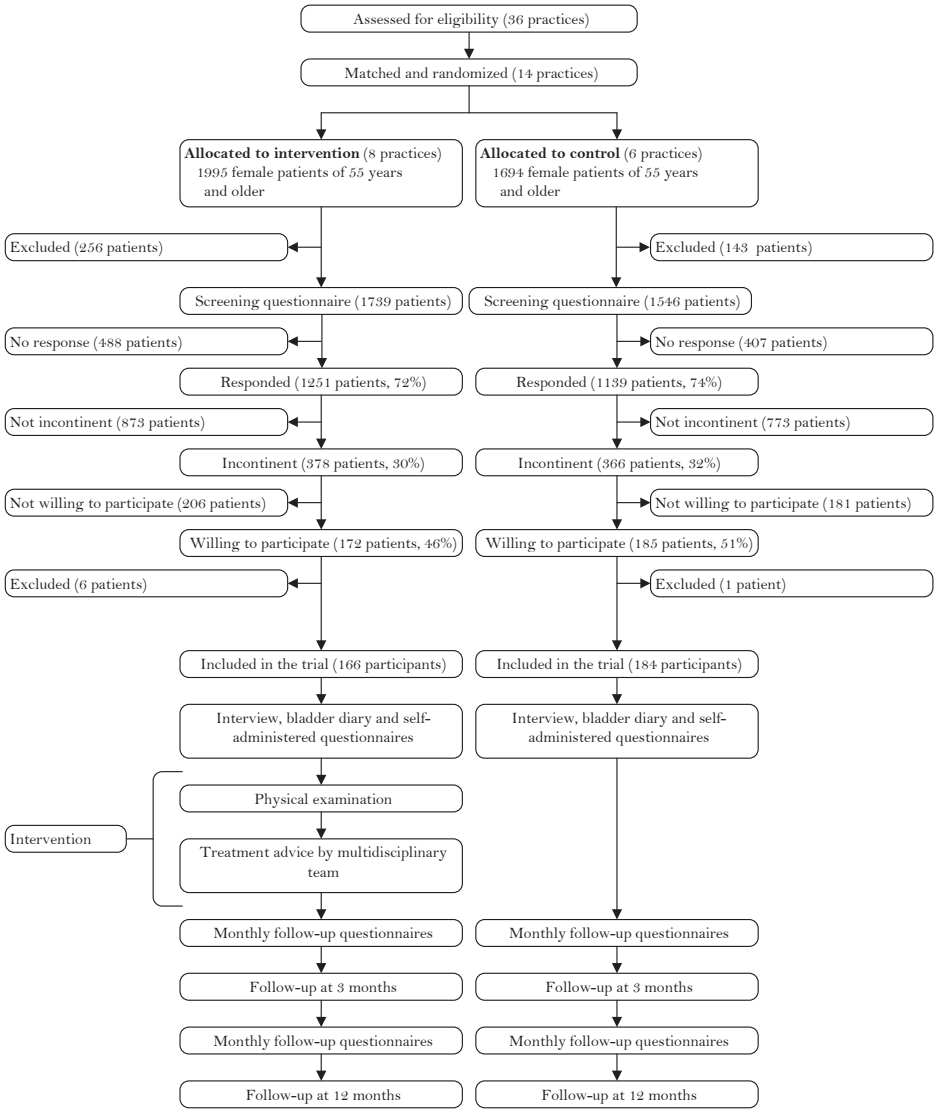

Figure 2 Flowchart of the URINO trial.

considerations, makes suggestions for further research, and considers the implications of this work for healthcare practice.

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CHAPTER 2

The effect of systematic screening of older women for urinary incontinence on treatment uptake: The URINO trial

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Maturitas 2013; 74: 334-340.

ABSTRACT

Background

Female urinary incontinence is a common condition that has a negative influence on quality of life and generates high costs, but spontaneous help-seeking is limited. In the URINO trial the effects and cost-effectiveness of actively encouraging older women to undergo diagnostics and treatment for urinary incontinence were compared with usual care.

Objectives

To describe the design of the URINO trial and to give data on the effect of treatment uptake after screening. In the discussion, the criteria of Wilson and Jungner are applied to discuss whether screening for urinary incontinence is suitable.

Methods

In a cluster randomized trial all registered female patients aged ≥55 years received a screening questionnaire. The intervention consisted of actively encouraging women to undergo diagnostics, after which tailored treatment was offered. In the control group care as usual was offered, but uptake of diagnostics and treatment was not encouraged.

Results

The response rate was 76%. 31% reported urinary incontinence; of these, 47% was willing to participate. All patients in the intervention group underwent diagnostics and treatment uptake was 80%; in the control group this was 2%.

Conclusion

To increase treatment uptake, screening must be followed by active encouragement for further diagnostics and treatment. Based on the principles of Wilson and Jungner, female urinary incontinence is a condition suitable for screening. The effect of treatment however needs further evaluation before screening can be recommended. The results of the URINO trial will fill this gap in knowledge.

INTRODUCTION

Female urinary incontinence is a common health problem that has a prevalence rate that increases significantly with age; about 33–44% of women aged ≥60 years report to be suffering from involuntary loss of urine[1]. Urinary incontinence has a negative influence on quality of life and, although effective treatments are available, only a minority of the affected women consult a professional[2]. Barriers to seeking help are feelings of shame, the belief that involuntary loss of urine is a natural part of aging, and that there are no treatment options[2]. Physician-related factors may also hamper the utilization of incontinence treatments, e.g. lack of knowledge about treatment effects in older women and not feeling confident to discuss the problem[3]. In addition, urinary incontinence generates high costs. In the Netherlands, in 2010 a total of €167 million was spent on incontinence pads[4].

In the URinary INcontinence in Older women (URINO) trial we studied the effect and cost-effectiveness of actively encouraging older community-living women with urinary incontinence to undergo diagnostics and treatment. All female patients aged ≥55 years, registered in the participating general practices, received a screening questionnaire about symptoms of urinary incontinence. The intervention consisted of actively encouraging women to undergo diagnostics and treatment, where in the control group no further activities were undertaken. It has been suggested, however, that asking for urinary incontinence alone could decrease the burden of urinary incontinence, because it makes women aware of their condition and this awareness will make them seek further treatment[5].

In the underlying paper, the study design of the URINO trial will be described, the results on the effect of screening on treatment uptake will be presented and we will discuss whether urinary incontinence is a condition to screen for in the light of the 10 criteria for responsible and acceptable screening as formulated by Wilson and Jungner[6]. As far as we know, a trial on screening and treatment uptake in urinary incontinence in older women has never been done before and it is meaningful to evaluate it by means of the criteria of Wilson and Jungner.

METHODS

Design

In a cluster randomized trial, family physicians were randomized instead of patients. The trial is registered in the Netherlands Trial Register (NTR1181) and was approved by the Medical Ethical Review Committee of the University Medical Center

of Groningen. The work described in this article has been carried out in accordance with the Declaration of Helsinki.

Intervention

The intervention consisted of active encouragement of the patient to undergo diagnostics and treatment: the patients were invited to undergo a physical examination and encouraged to get treated.

Setting

In the URINO trial patients were recruited from primary care practices in the northern part of the Netherlands. In the Netherlands, all patients are enlisted in one primary care practice and patients need to be referred by their family physician before they can visit a secondary care specialist.

Randomization

After agreeing to participate, family physicians were matched into pairs, based on urbanization grade, age and sex. Within each pair, family physicians were randomly allocated to either the intervention or control group. The patients, the research assistants and the family physicians were not blinded for the assigned group.

Systematic screening of the study population

Each participating family physician reviewed a list of all women aged ≥55 years in his or her practice. Patients were excluded if they had overflow incontinence, were suffering from malignancies, were already being treated for a urogynecological condition, had an indwelling catheter, had severe dementia, or were in a poor physical condition (as assessed by their family physician, like severe comorbidity, poor mobility or in palliative phase of disease). All remaining women were sent a short postal questionnaire (Fig. 1) concerning urinary incontinence and their willingness to participate in the trial. The questionnaire is in line with the formal definition of urinary incontinence as formulated by the International Consultation of Incontinence (ICI) and has a good reproducibility and good agreement with a bladder diary[7]. Patients were eligible for the trial if they were able to fill in a questionnaire, if they experienced involuntary loss of urine, and if they gave informed consent. Fig. 2 presents a flowchart of the trial.

Baseline assessment

All women enrolled in the URINO trial were interviewed by a researcher about their medical history, were asked to complete a 3-day bladder diary, and to fill in self-administered validated questionnaires about the characteristics of their urinary

SCREENING FORM

Study of urinary incontinence

Please answer the following questions and return this form back to us in the enclosed envelope (even if you answered NO to question 1)

1. Do you have involuntary loss of urine, once a month or more often?
   YES → Question 2
   NO → Questionnaire finished, return in the enclosed envelope

2. How often do you leak urine?
   Once a week or less
   Two to three times a week
   About once a day
   Several times a day
   All the time
3. Are you interested to participate in the study? (See information leaflet)
   YES → We will contact you
   NO → Please explain why not:……..

Please return this form back to us in the enclosed envelope (no stamp required).

Thank you for your time!

Figure 1 Postal Screening Questionnaire

incontinence and their mental and physical health: ICIQ-UI SF and the ISI (symptoms and severity of urinary incontinence), UDI (symptom distress), IIQ-7 (disease specific quality of life), MOS SF-20 (general quality of life), EQ-5D (health outcome and utilities), GARS (functional status), GDS-10 (depression) and the SAQ and PISQ-12 (sexuality)[8-17].

Additional assessment in the intervention group

Patients in the intervention group were invited to undergo a physical examination performed by a trained research physician, which consisted of a supine and standing cough stress test with a naturally filled bladder, free uroflowmetry to measure maximum flow and voiding pattern, a standardized assessment of pelvic organ prolapse (by using the POP-Q system) and the pelvic floor muscle function[18-23].

Care in the intervention group

In the intervention group, the results of the baseline assessment of each patient were reviewed by a multidisciplinary expert team consisting of a family physician, a urologist, a gynecologist and a pelvic floor physiotherapist. This team of experts established the type of incontinence and recommended a patient tailored treatment.

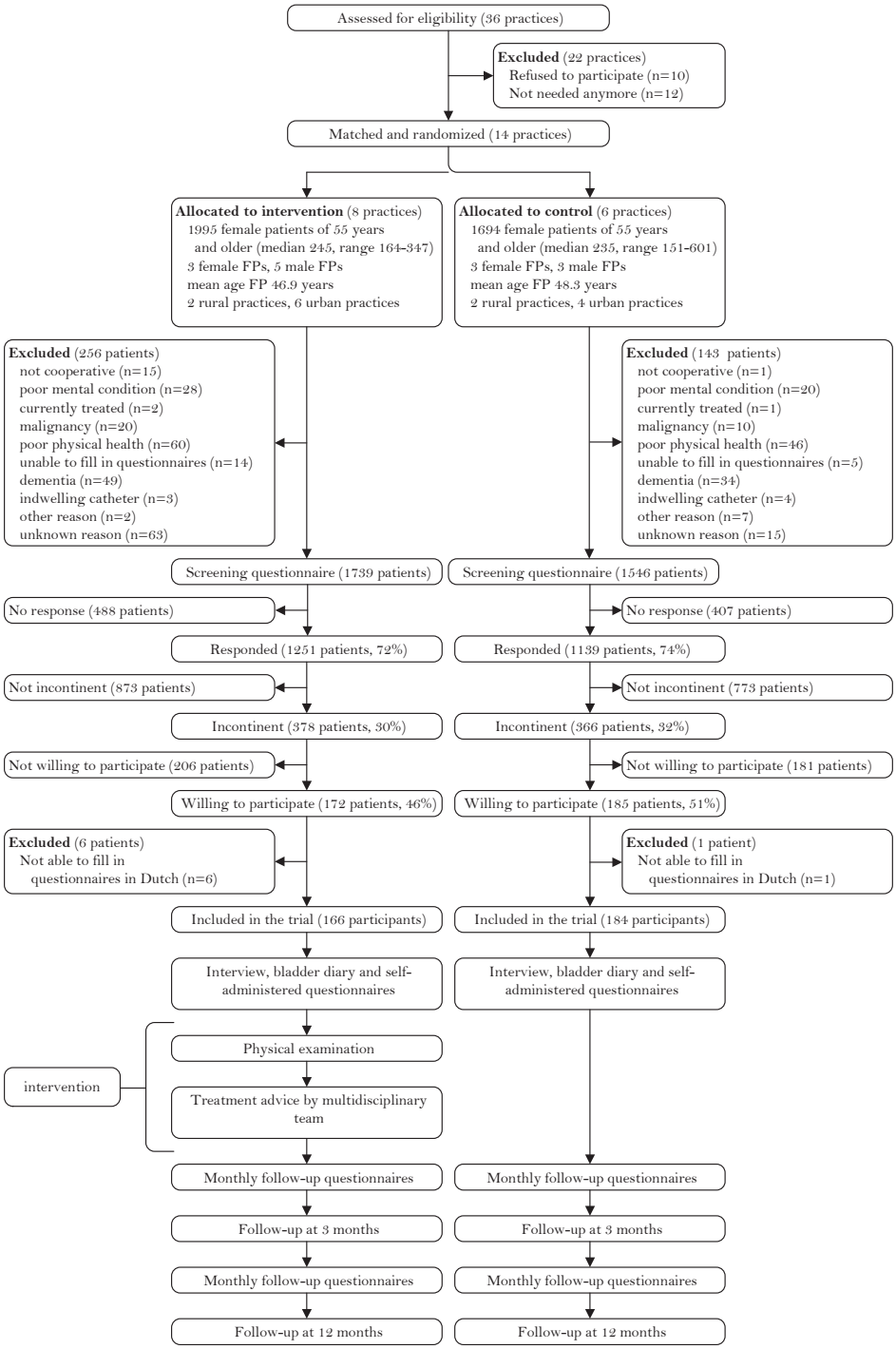

Figure 2 Flowchart of Clusters and Participants of the URINO Trial

Care in the control group

Women in the control group received standard care, implying that they were not actively encouraged to undergo diagnostics and treatment and that they only received care when they visited their family physician (care on demand)[24]. If asked for, diagnostics and treatment were according to the Dutch guideline for family physicians on urinary incontinence[24].

Follow-up assessment in both groups

Follow-up measurements were made at 3 and 12 months and included self-administered questionnaires about the symptoms of urinary incontinence, a 3-day bladder diary and a question about self-experienced changes in symptoms[8-17, 25]. In addition, patients were asked to complete a monthly four-item questionnaire including a question about changes in symptoms, two questions about the severity of the incontinence, and a question on the number of absorbent pads used per day[9, 25].

Outcome measures

The primary outcome was reduction in the severity of involuntary loss of urine after 12 months as measured with the ISI[9].

Secondary outcomes were the number of incontinence episodes (documented in the bladder diaries), the incontinence-specific quality of life (IIQ-7 score), the generic quality of life (MOS SF-20 scores) and the costs of the incontinence[11, 12]. Costs were derived from the case record form and from the patient questionnaires.

Sample size calculation

A clinically relevant effect was considered to be an improvement in one or more of the four categories on the ISI after 12 months. Based on previous research, this was expected for 65% of the patients in the intervention group and for 40% of the patients in the control group[26]. Given a significance level of 5% and a power of 80%, 70 patients per group were needed. Because of the cluster randomization, a correction for interdependence between patients per family physician was necessary. A correction factor of 1.4 was calculated based on the number of patients per family physician (10) and the variation between family physicians (0.1)[27]. Consequently, 98 patients per group were needed. Given a withdrawal rate of 20% (which is reasonable given the age of the patients), 123 patients per group had to be included.

Statistical and economic analysis

In the analysis, the intervention and control group were compared regarding baseline characteristics and clinical effects. The effect of treatment was analyzed with logistic regression models with correction for cluster randomization. A complete

case analysis was performed within the group of patients who fulfilled the complete follow-up period (complete cases). In a multiple imputation analysis, missing values were imputed.

In the economic evaluation, the balance between costs and effects was compared at 12 months follow up in a cost-effectiveness analysis[28]. Direct medical and non-medical costs over a 12-month period were included from a societal perspective: costs of the diagnostic and therapeutic consultations, GP visits, multidisciplinary consultation meetings, drug treatment, incontinence materials and traveling.

Data collection and analysis of the here presented results

The results from the screenings questionnaire of the URINO trial were used to calculate response rate, help-seeking rate, prevalence, therapy advice, and inclusion results and will be presented as numbers and percentages. Information on help-seeking behavior was derived from the first 225 patients that were included in the trial

RESULTS

In the period February 2008 to November 2010, 3285 screening questionnaires were sent to female patients (aged ≥55 years) of the 14 participating family physicians and 2390 (74%) forms were returned. In total, 744 (31%) women reported symptoms of urinary incontinence; of these, 350 (47%) consented to participate in the trial and all were included. Of the 105 patients in the intervention group with a complete dataset, 84 (80%) followed the treatment advice that was given by the multidisciplinary team. In the control group, 3 patients (of the 138 patients with a complete dataset; 2%) received therapy for urinary incontinence (started at their own initiative). Of the first 225 patients, 143 (64%) were found not to be known by their family physician as suffering from urinary incontinence.

DISCUSSION

The most distinguishing feature of the URINO trial is the systematic screening of the study population: a questionnaire was used to test whether women were suffering from urinary incontinence. Screening an older population for treatable conditions is in line with the current health policy of governments in which the focus is on 'healthy aging'. Screening for urinary incontinence might enable people who suffer from this condition to benefit from treatments with proven effectiveness. However, screening

has some drawbacks, even though the benefits seem obvious[29]. In 1968, 10 criteria for responsible and acceptable screening were formulated by Wilson and Jungner in a normative framework[6]. Below, we discuss our study in the light of these 10 criteria, to see whether urinary incontinence is a condition to screen for and what our trial can contribute to support screening.

1. Is urinary incontinence an important health problem? *PARTLY*

Urinary incontinence (with a prevalence of about one third of older women) is a common condition[1]. Although it is not a life-threatening disease, the condition can have a considerable negative influence on quality of life[30]. Nevertheless, only a minority seeks help: in the present study, 64% of the patients had not sought help for urinary incontinence[2]. In comparable studies this number ranges from 50 to 76%[31-33]. Particularly younger women seem reluctant to seek help[2, 34]. Based on the high response from the screening questionnaire (74%) and the percentage of patients willing to participate in the trial (47%), we conclude that at least a substantial part of the population of older women are willing to accept help in the context of a trial. More importantly, with active encouragement to undergo diagnostics and treatment, screening leads to treatment uptake in 80% of the patients, and without active encouragement in only 2%. So screening alone (without an invitation for diagnostics and treatment), did not lead to action from the screened population. Based on our trial, statements about the rationale for screening men for urinary incontinence could not be made, since men were not part of the URINO trial. It is known that prevalence rates and pathophysiology of urinary incontinence vary between men and women[35].

2. Is there an accepted treatment for patients with recognized disease? *YES*

Conservative treatments (e.g. lifestyle changes, pelvic floor muscle training, biofeedback, electrical stimulation and bladder training) have proven their effectiveness, also in the elderly[36, 37]. These interventions have few adverse effects and are suitable for patients with diverse characteristics and levels of severity of symptoms[36]. Prescription of drugs (e.g. anti-cholinergics or estrogens) is suitable for patients with urgency symptoms or postmenopausal women[36]. Surgical treatments are available in case of failure of conservative therapies.

3. Are there facilities for diagnosis and treatment of urinary incontinence available? *YES*

With careful clinical history to gain insight into the type of urinary incontinence and a physical examination aiming to reveal secondary causes of urinary incontinence, urinary incontinence is relatively easy to diagnose by a family physician. Also, the abovementioned non-surgical treatment options can be initiated from primary

care. If conservative treatments fail, or if the clinical history or physical examination reveals a severe underlying cause, diagnostic and therapeutic facilities in specialist care are available.

4. Is there a latent or early symptomatic stage? *UNCERTAIN*

There is evidence for prevention of incontinence in non-symptomatic pregnant women by conservative means[37]. However, the treatment of non-pregnant women at risk for urinary incontinence and without symptoms, is not yet supported by evidence. The URINO trial included women with all stages and severities of urinary incontinence, which might allow us to draw conclusions about the effect of treatment in women with early symptomatic and mild urinary incontinence.

5. Is there a suitable test for urinary incontinence? *YES*

A validated questionnaire to screen for urinary incontinence is lacking and known short validated questionnaires like the ISI and ICIQ, are more suitable for patients that are already diagnosed with urinary incontinence. Therefore, we systematically screened the study population by using the question: Do you have involuntary loss of urine once a month or more often? A question that is in line with the formal definition of urinary incontinence as formulated by the ICS, and has a good reproducibility and a good agreement with a bladder diary[7, 38].

6. Is the test acceptable to the population? *YES*

The screening test consists of a two-item questionnaire. Because the test is neither invasive nor time-consuming it is unlikely to give problems regarding acceptability. In the present study the response rate on the screening questionnaire was 73%, which supports our assumption.

7. Is the natural history of urinary incontinence understood? *UNCERTAIN*

Urinary incontinence mainly affects women and the prevalence increases significantly with age[1]. A few longitudinal studies that examined remission of urinary incontinence report that annual remission rates range from 7 to 9%[39, 40]. Urinary incontinence results from deficiency of the urethral closure mechanisms or from involuntary detrusor activity. Established risk factors for urinary incontinence are childbearing, obesity, other urinary symptoms and functional impairment[1]. Other factors likely to increase the risk of urinary incontinence are a history of childhood enuresis, high-impact physical activities, diabetes, stroke, depression, estrogen depletion, urogenital surgery and radiation. However, the natural history of urinary incontinence, especially how do established risk factors interact with each other and how does the course of urinary incontinence progress over time, needs further elucidation.

8. Is there an agreed policy concerning whom to treat as patients? *YES*

The policy is to treat every patient who has involuntary loss of urine. The stage and severity of symptoms do not guide the choice of whom to treat (or not treat), only how to treat. Unfortunately, several patient and family physician factors interfere with good management of urinary incontinence in the elderly[3].

9. Are the costs of case-finding economically balanced in relation to possible expenditure on medical care as a whole? *UNCERTAIN*

Screening generates costs and the question remains whether these costs balance the effects and savings due to a decrease in the use of absorbent products. This is one of the main topics of our URINO trial.

A limitation of our study is that we have no information on the non-responders who suffer from urinary incontinence. In a worst-case scenario, all these women have severe symptoms and generate high costs. A proportion of these non-responders will also be non-help seekers. Known factors associated with help-seeking are a higher age and higher levels of distress due to urogynecological symptoms[2]. The mean age in both the non-responders and responders was similar, i.e. about 70 years. Thus, hypothetically, levels of distress are on average higher among the non-responders compared with the responders. Our cost-effectiveness analysis will provide insight into whether these high levels of distress are also associated with high costs, and gives an impression of the costs among the non-responders.

10. Is case-finding a continuing process and not a "once and for all" project? *YES*

If the URINO trial shows a convincing effect of the intervention at reasonable costs, implementation of screening for urinary incontinence in primary care should be considered. A question about urinary incontinence could be part of the monitoring of chronic diseases, or included in a yearly medication review. A proactive healthcare provider and information campaigns for patients could improve help-seeking behavior. Education of healthcare providers and the presence of a nurse specialist in primary care for urinary incontinence might facilitate help-seeking by patients, make case-finding a continuing process and improve the diagnosis and treatment of urinary incontinence.

CONCLUSION

Screening among older women in primary care for urinary incontinence by asking a single question meets most internationally accepted criteria for screening as reported by Wilson and Jungner. But evidence for the utility of treating patients with urinary

incontinence at an early symptomatic stage is still lacking (criteria 4) and the natural history is not completely understood (criteria 7). Further research is needed to fill these gaps in order to answer the question whether screening on urinary incontinence is appropriate[41]. Whether or not screening for urinary incontinence is cost-effective (criteria 9) is one of the topics of our ongoing URINO trial.

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CHAPTER 3

Active encouragement of older women with urinary incontinence in primary care to undergo diagnosis and treatment: a matched-pair cluster randomized controlled trial

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ABSTRACT

Objective

Although the prevalence of urinary incontinence in older women is high, the condition is underdiagnosed and undertreated as the majority have not sought help. The URINO trial investigated the effect of offering treatment to women with urinary incontinence in the general population.

Design

In a cluster randomized trial, 14 general practitioners were matched into pairs and randomly allocated to an intervention or a control group.

Participants

Women aged ≥55 years registered in the participating practices were screened for urinary incontinence via a postal questionnaire.

Intervention

Participants in the intervention group were assessed and treated whereas participants in the control group received standard care.

Outcome measures

Primary outcome was improvement (yes or no) of the severity of symptoms at 12-months follow-up measured with the Incontinence Severity Index. Secondary outcomes were the number of incontinence episodes per day and quality of life. The primary analysis was on an intention-to-treat basis with multiple imputation of missing data. A logistic regression model with correction for cluster randomization was fitted to estimate odds ratios (ORs).

Results

At 12 months, the severity of symptoms had improved in more participants in the intervention group (n=166) than in the controls (n=184) (OR 1.9; 95%-CI 1.1-3.3). Also, the number of participants with fewer episodes of incontinence had increased (OR 2.5; 95%-CI 1.5-4.1). No differences in change of quality of life scores were found.

Conclusions

It is recommended to encourage women in the general population aged ≥55 years with urinary incontinence to undergo diagnosis and treatment.

INTRODUCTION

Urinary incontinence is a very common disorder in women. Most studies report a prevalence of 25-45% with approximately 10% of all adult women reporting involuntary leakage at least weekly[1, 2]. The prevalence of urinary incontinence increases with age and a rise in the number of incontinent patients is expected with the aging population. Three main subtypes of urinary incontinence are distinguished: stress incontinence, urgency incontinence, and mixed urinary incontinence. Although the condition is not life-threatening the impact on daily life can be great: it may cause social isolation, lack of self-esteem, feelings of shame and depression[1, 2]. Reasons given by women for not seeking help include: not regarding incontinence as a serious problem, considering incontinence to be a normal part of aging, having low expectations of treatment, thinking they should cope on their own, and embarrassment[4].

The recommended first-line treatment for urinary incontinence is pelvic floor muscle training (PFMT) for stress urinary incontinence, and bladder training and anticholinergic drug therapy for urgency urinary incontinence. In case of mixed urinary incontinence, starting a treatment directed to the most dominant symptoms of the urinary incontinence component is recommended[5]. It is unknown whether or not these treatments have the same effects in women who do not seek help on their own initiative as they have in women consulting for urinary incontinence.

The aim of this trial was to study the effects on severity of incontinence and quality of life of diagnosing and treating older community-dwelling women with urinary incontinence who were invited to receive treatment, and to compare this to the effects in a group of women receiving standard care[6]. The hypothesis is that women will benefit from the active approach in that it will reduce the severity of their urinary incontinence and improve their quality of life more than standard care alone.

METHODS

Trial design and participants

The URinary INcontinence in Older women (URINO) trial is a matched-pair cluster randomized controlled trial in primary care, performed in 14 general practices in the northern part of the Netherlands. The design of this study has been published elsewhere[7, 8]. In short, each participating general practitioner (GP) reviewed a list with all women aged ≥55 years (roughly 180 per GP) registered in his or her practice, to check the exclusion criteria: overflow incontinence, malignant diseases, currently being treated for urogynecological conditions, having an indwelling catheter, being severely demented, or in a poor physical condition. Being already known as suffer-

ing from urinary incontinence was not an exclusion criterion. All eligible women received a questionnaire on involuntary loss of urine; if they had involuntary loss of urine once a month or more, they were asked to participate in the trial. Other inclusion criteria were: being able to fill in a questionnaire in Dutch, and written informed consent. Enrollment took place between February 2008 and December 2009; the last follow-up measurement was made in July 2011.

The trial is registered in the Dutch Trial Register (registration number NTR1181) and approval was obtained from the Medical Ethical Review board of the University Medical Center Groningen (UMCG), the Netherlands.

Randomization and blinding

To prevent contamination, the participating GPs were matched into pairs based on their age and sex, and urbanization grade of the practice. Participating GPs did not shared practices. Within each pair, GPs were randomly allocated to either the intervention or the control group. In one case, three comparable small practices were taken together as one practice, to prevent unequal distribution of the number of participants per group. Randomization was performed with a random numbers table (using the SAS system for Windows) by a researcher not involved in the study and blinded for the identity of the practices. GPs, participants and research employees were not blinded for the allocated arms. The researcher who analyzed the data was blinded for treatment allocation.

Baseline assessment for all participants

All participants completed validated questionnaires on the severity of urinary incontinence (the Incontinence Severity Index, ISI) (Figure 1), urinary symptoms (Urinary Distress Inventory) and condition-specific and generic health-related quality of life (short form of the Incontinence Impact Questionnaire IIQ-7; and the MOS SF-20, respectively)[9-11]. These questionnaires measure patient-reported outcomes in urinary incontinence and are recommended by the ICI[12]. All participants were interviewed by a researcher for details of their medical history and all participants were asked to complete a three-day bladder diary. The number of incontinence episodes per day was derived from this bladder diary.

Assessments

Participants in the intervention group underwent a urogynecological examination by the research physician including a cough stress test (in supine and standing position, with a naturally filled bladder), uroflowmetry (with a naturally filled bladder, to measure maximum flow and voided volume), post-void residual measurement (with a Bladderscan®), urinalysis for urinary tract infections (with a dipslide), a pelvic

Questions used to assess the degree of urinary incontinence in women:

1 How often do you experience urinary leakage?
   a. Less than once a month
   b. A few times a month
   c. A few times a week
   d. Every day and/or night

2 How much urine do you lose each time?
   a. Drops
   b. Small splashes
   c. More

The Incontinence Severity Index is created by multiplying the results of question 1 and 2 and then categorizing it:

1-2 Slight
3-6 Moderate
8-9 Severe
12 Very severe

Figure 1 Incontinence Severity Index (the primary outcome measure of the URINO trial)

examination with a standardized assessment of urogenital prolapse (POP-Q system), and an assessment of the pelvic floor muscle function[13-17]. A multidisciplinary team (consisting of a urologist, gynecologist, pelvic floor physiotherapist, and a GP) discussed the clinical and questionnaire findings and formulated the diagnosis and a treatment plan[18].

Follow-up measurements were made at 3 and 12 months and included self-administered questionnaires and a bladder diary[9-11]. In addition, patients were asked to complete a short monthly questionnaire[9].

Participants in the control group received standard care according to the Dutch Guidelines for General Practitioners, implying that diagnosis and treatment took place only when the participant decided to consult her GP for urinary incontinence[6].

Potential side-effects of any treatment were registered in the case record forms.

The primary outcome was improvement in the severity of urinary incontinence 12 months after the start of the treatment (intervention group) or after baseline (control group). Secondary outcomes were the number of incontinence episodes per day, the incontinence-specific quality of life (IIQ-7 score), and the general quality of life (MOS-SF-20 score). Improvement was defined as a category (ISI) or score (incontinence frequency, IIQ-7 and MOS-SF-20) at follow-up that was better than that at baseline.

In the intervention group, the 12-month follow-up period started on the first day of the treatment; in the control group this started on the day of inclusion.

Sample size

Improvement in the severity of the incontinence was estimated to occur in 65% of those in the intervention group and in 40% of those in the control group[19]. Given a significance level of 5% and a power of 80%, 70 participants per group were needed. Because of the cluster randomization a correction factor of 1.4 was applied, based on the estimated number of participants per cluster (10) and the variation between the GPs (0.1)[20]. This meant that 98 participants per group were needed for analysis. With an expected loss to follow-up in this age group of 20%, 123 participants per group had to be included in the study.

Statistical analysis

The intervention and control group were compared regarding the improvement of severity of incontinence symptoms, improvement in the number of incontinence episodes per day, and improvement of incontinence-specific and general quality of life. Outcome parameters were dichotomized to be able to perform logistic regression analyses with correction for matched pairs clustering and to calculate odds ratios (ORs) with 95%-confidence intervals (CIs). The primary analysis was an intention-to-treat analysis including all participants. Missing data were imputed with a multiple imputation analysis, based on the baseline and treatment characteristics of the entire group of participants. Two sensitivity analyses were foreseen for the primary outcome measurement, the improvement in ISI category: a complete-case analysis among participants with a complete dataset at follow-up, and a multiple imputation analysis based on the success rates of the control group alone (no other variables involved), assuming that there was no treatment effect for the participants with missing outcomes. The second imputation analysis was planned to evaluate the missing at random (MAR) assumption, underlying the primary analysis. Data were analyzed with the SPSS version 20.0 for Windows. Statistical significance was set at a p-value <0.05.

RESULTS

The 14 participating GPs sent 3,285 screening questionnaires to their female participants aged ≥55 years and 2,390 (74%) were sent back (Figure 2). Among the responders, 744 (31%) women reported symptoms of urinary incontinence and 350 (47%) of this group consented to participate in the trial and were included.

At baseline, the intervention and the control group were comparable (Table 1).

In the intervention group, of the 166 women, the clinical and questionnaire data of 153 women were discussed by the multidisciplinary team; 13 women decided to

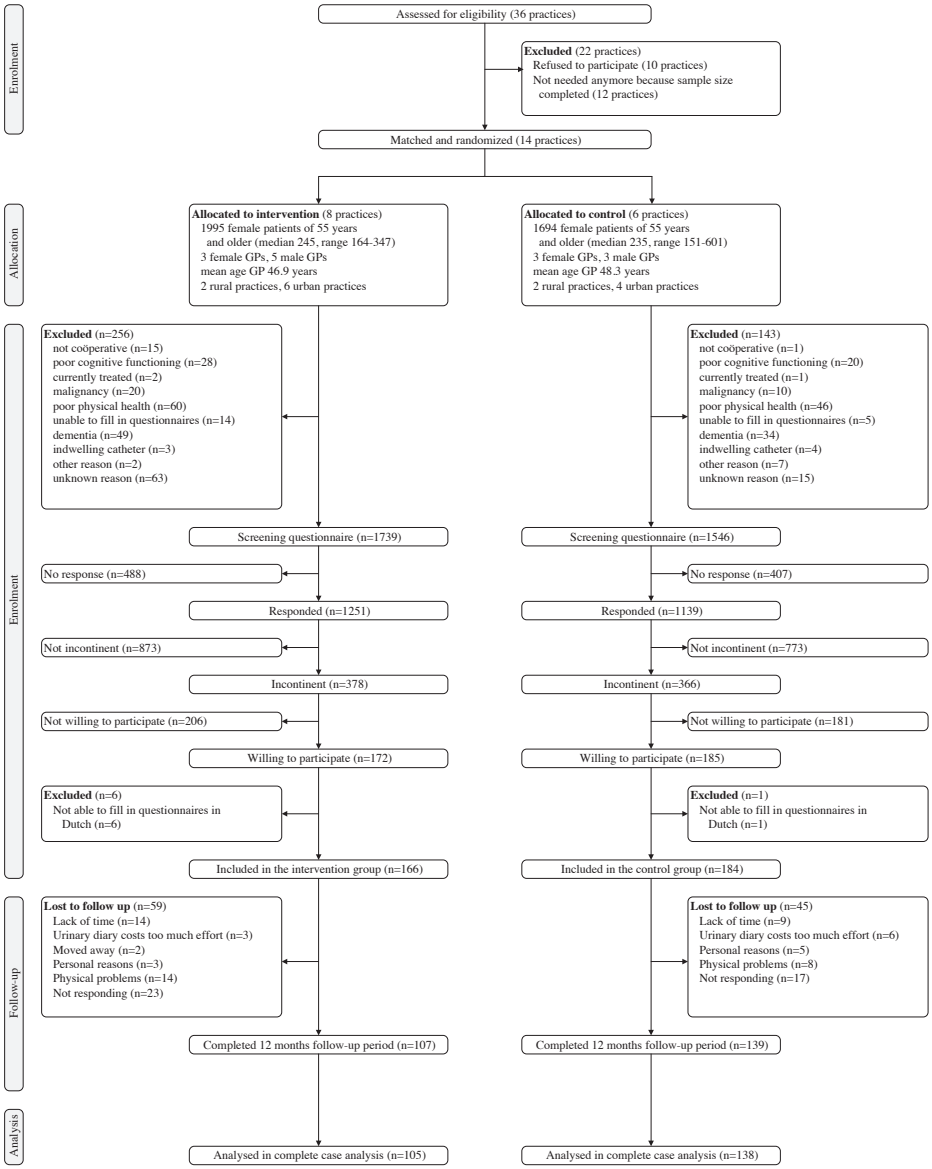

Figure 2 Flowchart of the clusters and participants

stop with the study before a treatment advice was given. After the evaluation, 75 women (49%) were referred for PFMT. A total of 41 women (27%) were referred to secondary care for further diagnostic examinations, of which 30 were still referred for PFMT. Thus, PFMT was the first-line therapy in 105 women (69%). The average number of treatments was 7 (range 1-19). Six women (4%) were treated with medication, 4 (3%) received a pessary, and 3 women (2%) underwent surgery. In the control

group, 3 women (2%) received a treatment: 2 received PFMT and 1 was prescribed an anticholinergic drug. The other participants in the control group did not seek help.

At the end of the follow-up period, 257 participants (73%) were still in the study and 254 of them had complete data regarding the primary outcome measurement. The major reason for leaving the study was that participation required too much time and effort, especially the keeping of a three-day frequency volume chart.

In the primary analysis of the main outcome measure (improvement in the ISI category), six imputation datasets were sufficient to obtain a high enough relative efficiency; they were pooled following Rubin's rule[21]. This analysis showed a nearly two-fold increase in the probability of a reduction in the severity of incontinence in the intervention group compared with the control group (OR 1.9; 95%-CI 1.1-3.3) (Table 2). In the first sensitivity analysis with participants with a complete dataset, the number of participants that had improved one or more categories on the ISI at follow-up was 36 (34%) in the intervention group and 24 (17%) in the control group (OR 2.4; 95%-CI 1.3-4.5) (Table 2). In the second sensitivity analysis with imputations based on the success rates in the control group of the six GP clusters, comparable results were found (OR 2.0; 95%-CI 1.1-3.4); this implies that the MAR assumption is plausible.

More than 25% of the included women had only mild symptoms (ISI score ≤ 2). For this reason, we did a secondary complete-cases analysis with women who had at least moderate to severe symptoms. In this latter analysis we found an improvement of one or more categories in 47% (36/76) of the women in the intervention group and in 24% (24/99) in the control group (OR 2.8; 95%-CI 1.4-5.3).

The median number of incontinence episodes per day decreased from 1.0 to 0.0 in the intervention group whereas it remained at 1.0 episode per day in the control group. The probability of improvement was more than doubled for the intervention group as compared to the control group (OR 2.5; 95%-CI 1.5-4.1) (Table 2).

The disease-specific quality of life (IIQ-7) improved during follow-up in both groups, but to a greater extent in the intervention than in the control group. However, after multiple imputation of missing values with correction for baseline scores, a non-significant difference was found in the change on the total IIQ score of 2.6 points (95%-CI -6.2-1.0). Only the score on the emotional health subdomain showed a significantly larger change in the intervention group. After dichotomization, the proportion of participants who showed an improvement on this quality of life score was not significantly different between the groups (OR 1.5; 95%-CI 0.8-3.1). For the generic quality of life scores (MOS SF-12), no differences in change were found (Table 2).

No side-effects of the treatments were reported.

Table 1 Baseline characteristics of the study population of female patients aged ≥ 55 years with urinary incontinence (n=350)

	Intervention group n=166	Control group n=184	p-value
Menopause age in years; mean (SD)	50·2 (4·8)	48·9 (5·5)	0·02*
Years since menopause; mean (SD)	15·6 (10·4)	16·5 (9·7)	0·45*
Parity; median (IQR)	2·0 (2·0-3·0)	2·0 (2·0-3·0)	0·71†
Self-reported type of incontinence ‡			0·42§
Stress incontinence; n (%)	44 (26·5)	53 (28·8)	
Urgency incontinence; n (%)	36 (21·7)	29 (15·8)	
Mixed incontinence; n (%)	82 (49·4)	94 (51·1)	
Other; n (%)	4 (2·4)	8 (4·3)	
Urinary Distress Inventory score			
overactive bladder; median (IQR)	44·4 (22·2-66·7)	44.4 (22.2-66.7)	0.29†
urinary incontinence; median (IQR)	26·7 (13.3-53.3)	26.7 (20.0-46.7)	0.98†
discomfort and pain; median (IQR)	11.1 (0.0-33.3)	5.6 (0.0-22.2)	0.22†
pelvic organ prolapse; median (IQR)	0.0 (0.0- 0.0)	0.0 (0.0- 0.0)	0.92†
obstructive micturition; median (IQR)	0.0 (0.0-50.0)	0.0 (0.0-33.3)	0.36†
bed-wetting; median (IQR)	0.0 (0.0- 0.0)	0.0 (0.0- 0.0)	0.87†
Age at baseline in years; mean (SD)	65.7 (8.4)	65.9 (8.3)	0.98*
Comorbidity ‖; median (IQR)	3.0 (2.0-5.0)	3.0 (1.0-4.0)	0.13†
Incontinence Severity Index			0.60§
Slight; n (%)	40 (24.1)	53 (28.8)	
Moderate; n (%)	83 (50.0)	90 (48.9)	
Severe; n (%)	35 (21.1)	36 (19.6)	
Very severe; n (%)	8 (4.8)	5 (2.7)	
Number of incontinence episodes per day; median (IQR)	1.0 (0.0-4.0)	1.0 (0.0-3.0)	0.47
Incontinence Impact Questionnaire score			
physical activity; median (IQR)	0.0 (0.0-16.7)	0.0 (0.0-16.7)	0.88†
travel; median (IQR)	0.0 (0.0-33.3)	0.0 (0.0-33.3)	0.66†
social and relationship; median (IQR)	0.0 (0.0-16.7)	0.0 (0.0-16.7)	0.94†
emotional health; median (IQR)	0.0 (0.0-16.7)	0.0 (0.0-16.7)	0.17†
overall; median (IQR)	4.8 (0.0-19.1)	4.8 (0.0-19.1)	0.93†
Medical Outcome Score			
physical functioning; median (IQR)	83.3 (37.5-100.0)	83.3 (50.0-100.0)	0.83†
role performance; median (IQR)	100.0 (50.0-100.0)	100.0 (50.0-100.0)	0.81†
social functioning; median (IQR)	100.0 (60.0-100.0)	100.0 (80.0-100.0)	0.79†
mental health; median (IQR)	56.0 (52.0- 60.0)	56.0 (52.0- 64.0)	0.07†
experienced health; median (IQR)	75.0 (50.0- 90.0)	75.0 (55.0- 90.0)	0.65†
physical pain; median (IQR)	50.0 (0.0- 75.0)	50.0 (0.0- 75.0)	0.57†

* t-test; † Mann Whitney U test; ‡ The clinical history for stress incontinence was defined as positive when a patient marked "leaks when you cough or sneeze" or "leaks when you are physically active/exercising" on the items in question 4 of the ICIQ. Urgency incontinence was diagnosed when a patient answers "yes" on question 3 of the UDI ("Do you experience urine leakage related to the feeling of urgency?"). Mixed incontinence was diagnosed when answers were positive for both stress and urgency incontinence. § Chi Square test; ‖ Number of diseases of the following list: recurrent urinary tract infections, kidney stones, urethral interferences, abnormal continence development, uterus extirpation, pelvic organ prolapse correction, diabetes, cerebral vascular incidents, myocardial infarction, angina pectoris, congestive heart failure, hypertension, atherosclerosis, COPD, dizziness with falling, severe or persistent back pain, joint problems, constipation, visual impairment, malignancies, and abdominal surgery.

Table 2 Primary and secondary outcomes in the intervention and control group at follow-up after one year

	Imputed data* Intervention group n=166 Control group n=184			Complete cases Intervention group n=105 Control group n=138					
	Improved OR (95% CI)	Difference in change between groups (95% CI)	p-value‡	Improved Intervention; n (%)	Improved Control; n (%)	OR (95% CI)	Numbers, median, c.q. change† Intervention	Control	p-value‡
ISI§	1.9 (1.1-3.3)			36 (34)	24 (17)	2.4 (1.3-4.5)			
Categories									
Slight							51 (56)	40 (29)	
Moderate							38 (37)	66 (48)	
Severe							14 (13)	29 (21)	
Very severe							2 (2)	3 (2)	
Incontinence Episodes	2.5 (1.5-4.0)			46 (54)	44 (37)		0 (0-2)	1 (0-2)	
IIQ-7‖									
Overall score	1.5 (0.8-3.1)	2.6 (-1.0-0.62)	0.14	41 (46)	40 (33)		-3.8 (9.5)	-0.4 (8.9)	<0.01
Subdomains									
Physical activity		1.0 (-1.8-4.7)	0.57	29 (29)	33 (25)		-4.3 (15.0)	-2.6 (15.9)	0.38
Travel		2.6 (-1.2-6.4)	0.76	20 (21)	18 (14)		-3.9 (13.9)	-0.3 (14.5)	0.06
Social and relationship		3.1 (-1.4-7.6)	0.17	14 (15)	14 (11)		-3.5 (17.8)	-0.0 (16.2)	0.13
Emotional health		3.3 (0.33-6.4)	0.03	27 (29)	19 (15)		-3.9 (12.9)	0.6 (10.9)	<0.01
MOS SF-20¶									
Subdomains									
physical functioning	1.3 (0.6-2.9)			10 (10)	21 (16)		6.1 (21.7)	3.5 (27.2)	0.43
role performance	1.7 (0.5-5.4)			8 (8)	9 (7)		-0.49 (34.3)	4.9 (34.3)	0.26
social functioning	1.1 (0.5-2.7)			15 (15)	24 (19)		-0.80 (18.6)	-0.46 (18.2)	0.89
mental health	1.2 (0.7-2.1)			37 (37)	47 (35)		-0.23 (7.5)	0.12 (8.8)	0.75
experienced health	1.3 (0.7-2.2)			35 (39)	55 (45)		0.81 (17.5	-3.0 (18.6)	0.13
physical pain	1.3 (0.8-2.3)			36 (36)	42 (32)		-13.0 (38.3)	-10.9 (32.4)	0.65

* Multiple imputation of missing values based on baseline characteristics of the entire group; ‡ t-test; § Incontinence Severity Index; ‖ Incontinence Impact Questionnaire-7; ¶ Medical Outcome Score Short Form-20; †number (%) of patients in the ISI categories after 12 months, median (IQR) number of Incontinence Episodes after 12 months and change (SD) on IIQ-7score and MOS-SF-20 score.

DISCUSSION

Main findings

This pragmatic, matched-pairs cluster randomized trial showed that, if older community-dwelling women with urinary incontinence are invited to be diagnosed and treated, the probability of improvement of the severity of symptoms after one year is two times higher than if they had received standard care. The probability that the number of incontinence episodes would decrease is more than doubled in the intervention group. No differences in change of quality of life scores were found.

Comparison with existing literature

In the present trial, the effects found (34% improvement in the intervention group, OR 1.9) are less than those reported by Dumoulin et al. in their systematic review on PFMT for urinary incontinence, although they did report a wide range of subjective cure rates (53-97%)[22]. In a review on non-surgical treatments for women with stress urinary incontinence, Imamura et al. found an OR of 4.5 for improvement or cure (95%-CI 2·0-11·9)[5]. Conservative treatment of urinary incontinence in women was shown to be effective by Shamliyan et al, although no pooled effect size could be estimated[23]. In our study, factors that might explain the relatively modest results are the age of the study population, the inclusion of all types of incontinence (results are generally better in stress incontinence than in urgency or mixed incontinence), the follow-up period of one year (most of the trials had a follow-up of 0.25-6 months; and results of PFMT are known to decrease over time)[22, 24, 25]. Furthermore, in our trial, more than 25% of the women had only mild incontinence, which limits the potential for improvement.

No trials with a population-based recruitment of older women were found with which to compare our study. Other studies on older women included referred participants, were clinic based and required urodynamic confirmation of stress incontinence, were ´recruited through local advertisements and professional referrals´ and ´predominantly urge incontinent´, or were recruited from university gynecological practices and included after urodynamic investigation[5, 26-29]. Dougherty et al. recruited women 'from seven rural north Florida counties' who had urine loss at least twice a week and were aged ≥55 years; however, it is unclear how they were selected[30]. The intervention group received a comprehensive behavioral intervention in their own home; after 12 months Dougherty et al. found a significant decrease of incontinence episodes per day as compared to no treatment[30].

In the present study no significant difference was found in mean change in disease-specific quality of life score after imputation of missing values, except for the emotional subdomain; in addition, no significant difference was found in the percentage

of improved participants. This means that, in our population, we could not show an effect of the intervention on the quality of life. Many women had a low baseline score on the quality of life questionnaires, implying that they experienced little impact of the incontinence on their daily life; this corresponds with the fact that many women in our trial had only mild symptoms. Explanation for the findings on the quality of life in our study and other trials may be that many women with urinary incontinence have found ways to cope with their problems and have adapted their activities to their condition[4]. Another explanation might be that the quality of life in older women is more defined by comorbid factors than by urinary incontinence[31].

Strengths and limitations of the study

The present study adds support to the effectiveness of diagnosing and treating older women with urinary incontinence that do not visit a GP on their own initiative. In view of the high response and participation rates, the active approach in our trial was apparently appreciated by the participants[7]. More than two thirds of the participants had never visited their GP with symptoms of incontinence[4]. With a follow-up period of one year, this is one of the few studies on incontinence reporting effects on the longer term.

This study was a cluster randomized trial: GPs were matched into pairs and then randomized to treatment or control, instead of randomizing participants. This may have influenced the decision of the participants to participate in the trial, because they knew in advance which arm of the trial their GP was allocated to[32]. However, no imbalances between the groups were observed at baseline.

Participants in the control group were of course informed about the study and were, thus, aware of the treatment options for incontinence offered in the intervention arm; this may have reduced the barriers for their seeking help. However, only 3 of them sought help of their own volition. This might mean that an invitation for treatment is essential to increase the number of incontinent participants that may receive adequate care.

The dropout rate in our study was higher than expected (30% instead of 20%). The main reason given for stopping was the 'demands made by the trial'. In comparison, a recent trial on pelvic organ prolapse had a dropout rate of 34% at one year[33]. However, our two analyses using different ways of imputing missing data had comparable results; this makes the findings on the effect of the intervention rather robust for missing data.

Implications and further research

Inviting older women with urinary incontinence who did not visit their GP for this problem, and then treating them, is effective, i.e. a treatment tailored to their needs

gives a twofold chance of improvement of symptoms. However, in the present study the percentage of participants that improved is relatively modest. One explanation for this is that over 25% of the included women had relatively mild symptoms. Nevertheless, we think that the evidence is strong enough to conclude that older incontinent women should be stimulated to seek help and that GPs should be convinced that 'therapeutic nihilism' is not justified in this group of patients. In care systems that do not yet provide in this, enquiring about incontinence at annual checks for chronic conditions can be a first step in the process of identifying more women with urinary incontinence. Patients should be explained what the diagnosis and treatment of urinary incontinence involves and how probable it is that their symptoms will improve. Then, as a shared decision, they can decide whether to follow this path or not.

Future research should focus on how to identify women with an impact of symptoms severe enough to warrant treatment and how to stimulate them to seek help.

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CHAPTER 4

Cost-effectiveness of actively encouraging older community-dwelling women with urinary incontinence to undergo diagnostic testing and treatment: a cluster randomized controlled trial

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ABSTRACT

Objective

Actively encouraging older community-dwelling women with urinary incontinence to be diagnosed and treated almost doubles the probability of a reduction in the severity of symptoms as compared with usual care. However, the balance between these health effects and the costs involved in order to gain these benefits remain unknown.

Design

A cost-effectiveness analysis (CEA) and a cost-utility analysis (CUA) were performed alongside a cluster randomized controlled trial, from a societal perspective, based on prospectively collected data. Direct medical and non-medical costs were taken into account, valued according to the standard Dutch guidelines for economic evaluations.

Setting

Primary care.

Participants

A total of 350 community-dwelling women aged ≥ 55 years with urinary incontinence, registered with 14 general practices.

Interventions

Patients in the intervention group were invited for diagnostic testing and treatment. The control group received usual care according to the Dutch guidelines. The follow-up period was 12 months.

Main outcome measure

Outcome in the CEA was based on the impact of urinary incontinence on daily life (the Incontinence Impact Adjusted Life Years; IIALYs). Outcome in the CUA was based on the Quality- Adjusted Life-Years (QALYs). Incremental costs were calculated per IIALY gained (ICER) and per QALY gained (ICUR).

Results

Costs per extra life-year without impact on daily life from urinary incontinence amounted to €5,179 (95%-CI: -17,323 to 36,260). Costs per QALY amounted to €23,907 (95%-CI: -124,849 to 121,849). Assuming a ceiling ratio of €20,000, the probability that the intervention was cost-effective based on IIALYs was 91% compared with 46% based on QALYs.

Discussion

The positive clinical effect of actively encouraging older women with urinary incontinence to undergo diagnostic testing and treatment can be achieved against reasonable costs, with an improvement of symptom-specific quality adjusted life years. Therefore, it is recommended to implement this proactive approach in general practice.

INTRODUCTION

Urinary incontinence, with a reported prevalence of at least 28%, is a very common condition among older women[1]. With the aging of the population its impact on the elderly in particular, and on society in general, is expected to increase. Although it is not a life-threatening condition, the consequences of urinary incontinence on a patient's life can be substantial: it may cause social isolation, lack of self-confidence, shame and depressive feelings[2, 3]. Overall, it causes a decrease in the quality of life[2]. Due to the low level of help-seeking behaviour among the affected population and, among general practitioners (GPs) the possibility of therapeutic nihilism, lack of time and lack of knowledge, evidence-based treatment options like pelvic floor muscle exercises and bladder training are underused and potential health gains are lost[4-6]. Instead of seeking professional help, many women cope with their symptoms by using incontinence pads[6]. In the Netherlands, in 2012 a total of €162 million (approximately € 9.7 million per million inhabitants) was spent on incontinence pads[7]. As urinary incontinence tends to gradually worsen with increasing age, a huge amount of incontinence pads will be used during a lifetime[8].

Besides these basic personal costs, urinary incontinence also leads to high costs for society, arising from psychological distress and impaired physical or mental health. For example, annual indirect costs (payments made by the employer for disability claims and imputed wages for medical-related work absence days) for stress urinary incontinence for the USA in 1998 were estimated to be $4208 per person per year[9].

Thus, apart from urinary incontinence being burdensome for the patient and causing health losses, it is also a costly condition for patients and society. The URINO trial (URinary Incontinence in Older women) showed that actively encouraging older women with urinary incontinence to undergo diagnostic testing and treatment, in a population not seeking help before, was associated with a statistically and clinically significant improvement of the severity of incontinence and the number of episodes of incontinence per day. In that trial, an improvement of severity of symptoms was found in 34% of the patients in the intervention group and in 17% of the control group (OR 1.9; 95% CI: 1.1 to 3.3); moreover, the median number of incontinence episodes per day decreased from 1.0 to 0.0 in the intervention group whereas it remained at 1.0 episode per day in the control group (OR 2.5; 95% CI 1.5 to 4.0)[10]. To assess the costs of actively encouraging older community-dwelling women with urinary incontinence to undergo diagnostic testing and treatment, and to examine whether this is a cost-effective strategy, a cost-effectiveness analysis (CEA) using data from the URINO trial was conducted.

METHODS

The URINO trial

The current economic evaluation was performed alongside the URINO trial. This is a cluster randomized controlled trial in which the effect of active encouragement of older community-dwelling women with urinary incontinence to undergo diagnostic testing and treatment was compared with usual care[10, 11]. The design of this trial and the clinical results are published elsewhere[10, 11]. In short, all women aged 55 years and older from 14 general practices were invited to complete a questionnaire measuring symptoms of urinary incontinence and were asked if they were willing to participate in the URINO trial. Women were eligible for inclusion if they reported involuntary loss of urine at least once a month, were able to fill in a questionnaire in Dutch and had given informed consent. Exclusion criteria were overflow incontinence (according to the medical file of the patient), malignancies, current treatment for urogynaecological conditions, an indwelling catheter, severe cognitive problems, or a poor physical condition according to their GP.

Pairs of GPs, matched on sex, age and urbanization grade of the practice, were randomized[12]. In total, 350 patients registered in 14 general practices participated in the trial (Table 1).

All participants filled in questionnaires and kept a 3-day urinary diary[13-22]. The participants of the intervention group underwent a physical and urogynaecological examination with additional tests, including a cough stress test, uroflowmetry, post-void residual measurement, urinalysis, pelvic organ prolapse quantification and examination of the pelvic floor muscle function[23-26]. Subsequently, they received an evidence-based treatment plan which was based on the evaluation of a multidisciplinary team (consisting of a GP, a urologist, a gynaecologist and a pelvic floor physiotherapist). Patients could be offered all evidence-based treatment options for urinary incontinence, including referral to secondary care for further diagnostic testing or treatment. In the control group, participants received care as usual, according to the guidelines of the Dutch College of General Practitioners[27]. Follow-up measurements were made at 3 and 12 months, and consisted of self-administered postal questionnaires. Figure 1 is a flowchart of the inclusion of participants in the URINO trial.

The trial was registered in the Dutch Trial Register (registration number NTR1181) and was approved by the Medical Ethical Review Committee of the University Medical Center of Groningen, the Netherlands.

Outcomes

The impact of urinary incontinence on daily life was measured with the Visual Analogue Score (VAS) of the International Consultation on Incontinence Questionnaire (ICIQ). This question was formulated as: "Overall, how much does leaking urine interfere with your everyday life?" The score ranged from 0 (no interference at all) to

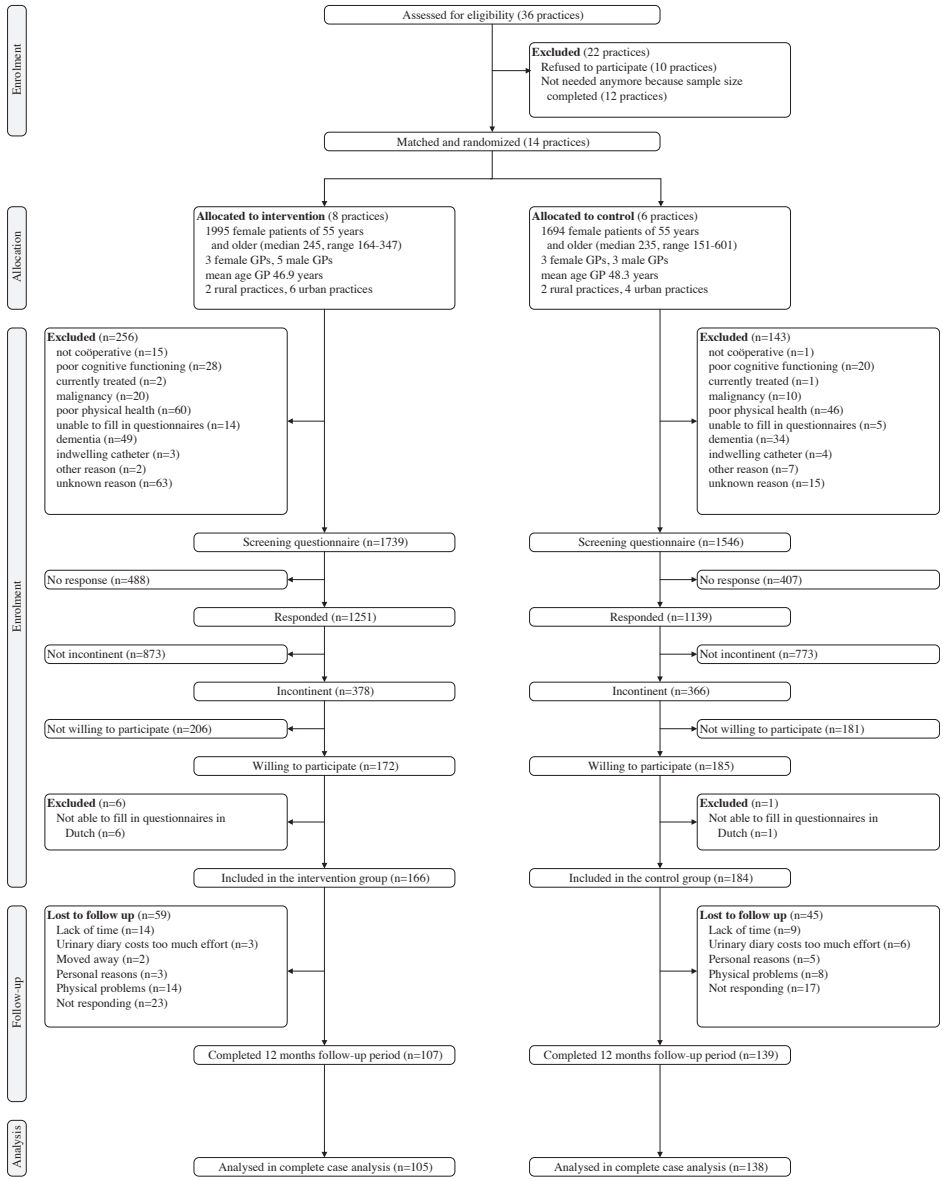

Figure 1 Flowchart of the study population.

10 (great interference)[13]. The EuroQol-5 Dimensions (EQ5D, scale from -0.33 (severe problems on all domains) to 1 (no problems)) questionnaire was used to measure generic quality of life and utilities[17, 28]. After inclusion in the trial, both the ICIQ and the EQ5D questionnaires were taken at baseline, and again at 3 and 12 months post-baseline.

In the current economic evaluation, the primary measure of effect was the impact on daily life of the incontinence symptoms, as measured by the Incontinence Impact Adjusted Life-Years (IIALY) score, derived from the impact score of the ICIQ[13]. The IIALY score was developed in order to obtain disease-specific quality of life weights and is considered to be a disease-specific Quality Adjusted Life-Years (QALY) score[29]. To be able to calculate this, the score on question 3 of the ICIQ ("Overall, how much does leaking urine interfere with your everyday life? Please ring a number between 0 (not at all) and 10 (a great deal)") was linearly transformed to a score between 0 (no impact on daily life from urinary incontinence) and 1 (maximum impact on daily life from urinary incontinence) IIALY score by dividing it by 10:

$$IIALY\ score\ = \frac{score\ on\ question\ 3\ of\ the\ ICIQ}{10}$$

Utility (represented by QALYs) was reflected by the changes in the EuroQol-5 Dimensions (EQ5D) scores, valued by the Dutch EQ5D tariff[17, 28]. The EQ5D questionnaire is a generic quality of life questionnaire and weighted scores range from -0.33 (severe problems on all 5 dimensions) to 1 (completely healthy).

After the weights had been obtained, area-under-the-curves (AUC) were computed to calculate gained IIALYs and gained QALYs for each individual patient over the total 1-year follow-up period. The AUCs reflect the amount of time in a perfect health state (or time corrected for quality). Calculations are as follows:

$$AUC\ = \frac{\chi_0 + \chi_1}{2} * (t_1 - t_0) + \frac{\chi_1 + \chi_2}{2} * (t_2 + t_1)$$

Where χ is the EQ5D or IIALY weight per data collection point and t is the data collection point. T_0 indicates baseline, T_1 indicates 3 months post-baseline, and T_2 indicates 12 months post-baseline.

Costs

Costs of healthcare utilization were derived from the case record form on which the numbers of healthcare consultations are registered. A costs questionnaire was used

to gather information about over-the-counter medication, absorbent pads, pelvic floor physiotherapist consultations, and travel expenses.

Relevant cost components that were taken into account were costs deriving from the diagnostic and treatment phase (intervention group) and costs directly deriving from the condition: consultations with a specialist, GP visits, treatments by pelvic floor physiotherapists, multidisciplinary consultation meetings, drug treatment, incontinence materials, other costs (such as pessary use) and travelling. Due to the higher age of the study population, productivity losses were not included in the economic evaluation. Cost components were valued according to the standard Dutch guidelines for economic evaluations[30]. Because the time horizon of this study was 12 months, discounting was not applied. Table 2 presents a detailed overview of the cost components included and the cost prices used.

Analysis

The economic evaluation was conducted from a societal perspective and included direct medical and non-medical costs. In the economic evaluation the balance between the costs and the effects of the active encouragement strategy was evaluated compared with usual care, in a cost-effectiveness analysis (CEA). This CEA assessed the incremental costs per IIALY gained, and was expressed as an Incremental Costs Effectiveness Ratio (ICER). A cost utility analysis (CUA) was performed to evaluate the balance between the costs and QALYs; the outcome of this analysis was expressed as an Incremental Costs Utility Ratio (ICUR).

Costs and effects were recorded and calculated on an individual patient basis, after which the mean differences of effects and costs between the two study groups were calculated. Point estimates of the ICER and ICUR were computed by dividing the differences into mean effects and mean costs. Then, by performing 5000 bootstrap replications of the trial data, alternative confidence intervals, based on the 2.5^{th} and 97.5^{th} percentile were calculated. Cost-effectiveness (CE) planes were constructed to visualise the uncertainty surrounding the ICER and ICUR. Subsequently, a Cost-Effectiveness Acceptability Curve (CEAC) was constructed to show the probability that the intervention is cost effective over a range of willingness to pay thresholds.

For both the ICER and ICUR, data of patients with a complete cost-effect pair were used (n=178 and n=169, respectively).

We performed a sensitivity analysis with a scenario representing daily clinical practice outside the URINO trial setting. In the URINO trial, the multidisciplinary expert team gave treatment advice from their own occupational perspective; they referred the patients that they would assess in their own (secondary care) practice. In this scenario, costs in the intervention group were based on a hypothetical situation after implementation of the intervention; in this scenario there are no costs for mul-

tidisciplinary meetings and referral was made only for the specific reasons stipulated in the Dutch Guidelines for General Practitioners: i.e. previous conservative treatment was ineffective, severe pelvic organ prolapse, uncertain diagnosis, secondary care treatment necessary (in this trial: surgery for recurrent prolapse), complicated clinical history (in this trial: cervical trauma or urethra dilatations), very severe and disabling symptoms, concomitant faecal incontinence, and/or a strong preference of the patient.

In this type of study, in which GPs were randomized instead of the patients, cluster-specific methods should be used when analyzing the results[31]. Correction for cluster randomization was not applied, since the effect of clustering turned out to be negligibly small and the degree of uncertainty was already large[10].

Data were analysed with the SPSS version 18.0.3 and Microsoft Office Excel 2010.

Table 1 Baseline characteristics of the study population of female patients aged 55 years and over with urinary incontinence (n=350).

	Intervention group n=166	Control group n=184	p-value
Self-reported type of incontinence			0.42†
Stress incontinence; n (%)	44 (26.5)	53 (28.8)	
Urge incontinence; n (%)	36 (21.7)	29 (15.8)	
Mixed incontinence; n (%)	82 (49.4)	94 (51.1)	
Other; n (%)	4 (2.4)	8 (4.3)	
Age at baseline in years; mean (SD)	65.7 (8.4)	65.9 (8.3)	0.98*
Body Mass Index in kg/m²; mean (SD)	27.7 (5.3)	27.0 (4.9)	0.17*
Education level			<0.01†
Low; n (%)	51 (30.7)	30 (16.3)	
Medium; n (%)	74 (44.6)	79 (42.9)	
High; n (%)	41 (24.7)	75 (40.8)	
Incontinence Severity Index			0.60†
Slight; n (%)	40 (24.1)	53 (28.8)	
Moderate; n (%)	83 (50.0)	90 (48.9)	
Severe; n (%)	35 (21.1)	36 (19.6)	
Very severe; n (%)	8 (4.8)	5 (2.7)	

* t-test; † Chi-square test

RESULTS

Study population

In total, 350 patients were included: 166 in the intervention group and 184 in the control group. Mean age of all patients was 65.8 years. Table 1 presents the baseline characteristics of the study population. At baseline, both groups were comparable regarding the type and severity of incontinence, age, and body mass index (BMI); however, patients in the intervention group had a lower level of education compared with patients in the usual care group.

Health outcomes

In the intervention group, at baseline the mean VAS impact score was 2.60 and after 12 months was 1.77; for the control group these impact scores were 2.76 and 2.78, respectively. At 12-months follow-up, patients in the intervention group gained on average 0.80 IIALYs and the control group gained 0.74 IIALYs: with regard to

Table 2 Costs overview

Types of costs	Unit cost (€)	Source	Mean costs intervention group (SD)	Mean costs control group (SD)	Mean difference (95%-CI)
Health Care costs					
Specialist consultation	€129/consultation*	CRF	90 (183)	0 (0)	90 (50-129)
Specialist telephonic consultation	€14/telephone*	CRF	0 (3)	0 (0)	0 (0-1)
General practitioner	€28/consultation*	CRF	11 (19)	0 (0)	11 (6-15)
Pelvic floor physiotherapist	€36/consultation*	CRF	183 (163)	38 (183)	145 (94-196)
Multidisciplinary meeting	€75/meeting†	CRF	75 (0)	0 (0)	75 (75-75)
Medication	price/drug‡	CRF	6 (35)	1 (12)	5 (-3-12)
Other costs (pessary, etc.)	variable	CRF	0 (2)	0 (0)	0 (0-1)
Subtotal health care costs			*365 (277)*	*39 (183)*	*326 (255-396)*
Patient and family costs					
Travel costs	€0.20/km¶; €3.00 parking costs	CRF	25 (20)	4 (20)	21 (15-27)
Medication	price/drug**	CQ	2 (19)	5 (41)	-3 (-12-7)
Incontinence pads	price/pad**	CQ	25 (29)	40 (34)	-15 (-24–5)
Subtotal patient and family costs			*52 (43)*	*48 (55)*	*4 (-11-18)*
Total costs			*417 (305)*	*87 (209)*	*329 (251-408)*

CRF: Case Record Form; CQ: cost questionnaire

* Prices according to: Oostenbrink, JB. Guidelines cost studies 2010.

† Per patient 2 specialists, 1 physiotherapist and 1 general practitioner. 6 patients per hour.

‡ Prices according to: Pharmacotherapeutic Compass. Price per day by daily usage plus prescription costs of €5,99 per medication per 90 days.

§ Prices according to: Medical Service Netherlands

¶ Mean travel distances: 1.1 km to GP practice, 2.2 km to physiotherapist, 7.0 km to specialist

** Market prices

urinary incontinence, the intervention group gained 0.80 years in a perfect health state and the control group gained 0.74 years.

In the intervention group, the mean EQ5D score at baseline was 0.86 and was 0.87 at 12-months follow-up; in the control group these values were 0.85 and 0.83, respectively. The intervention group gained on average 0.86 QALYs and the control group 0.84; in a perfect health state the groups gained 0.86 and 0.84 years, respectively.

Cost comparison

Mean costs per patient over the complete 12-month follow-up period were €417 in the intervention group compared with €87 in the control group (Table 2). Main cost drivers in the intervention group were pelvic floor physiotherapy (€183 on average per patient) and, in the control group, incontinence pads (€40 on average per patient). At 12 months follow-up, patients in the intervention group had lower daily costs due to use of absorbent pads than the control group (€2.10 vs. €3.26).

Cost effectiveness

In the CEA, the mean difference in costs between the intervention group and usual care group was €329 and the mean difference in effect on gained IIALYs was 0.06 (Table 3): with regard to urinary incontinence, patients in the intervention group gained on average 0.06 years in a perfect state, with €329 additional costs. This resulted in an ICER of €5,179 (95%-CI: -17,323 to 36,260): to gain 1 IIALY on the

Table 3 Cost-effectiveness of active encouragement of community-dwelling older women with urinary incontinence to undergo diagnostic testing and treatment.

	Intervention group	Control group	Difference	ICER† (95%-CI)
	n=95	n=83		€5,179 (-17,323-36,260)
IIALYs gained*	0.80	0.74	0.06	
Costs	€417	€87	€329	
	intervention group	control group	difference	ICUR§ (95%-CI)
	n=83	n=86		€23,907 (-124,849-121,667)
QALYs gained‡	0.86	0.84	0.01	
Costs	€396	€84	€312	

* IIALYs: Incontinence Impact Adjusted Life-Years; † ICER: Incremental Cost Effectiveness Ratio; ‡ QALYs: Quality-Adjusted Life-Years; § ICUR: Incremental Cost Utility Ratio

population level (i.e. to let 1 person on average live 1 extra year in a perfect state with regard to their urinary incontinence) €5,179 needs to be invested. Most of the 5000 replications of the bootstrap simulation (i.e. 96% of them) were in the north-east quadrant, indicating that they represented a better outcome and higher costs (see Figure 2 for the incremental CE plane). The CEAC (Figure 3) shows that, with a

ceiling ratio of €20,000 (i.e. the maximum amount of money a decision-maker would be willing to pay), the probability that the intervention is cost effective would be 91%.

In the CUA we found that with a mean difference in costs of €312 and a mean difference of 0.01 in gained QALYs, the ICUR was €23,907 (95%-CI: -124,849 to 121,667) (Table 1 and Figure 4). This means that €23,907 needed to be invested to gain 1 QALY on the population level. Of the 5000 bootstrap replications, 62% was located in the north-east quadrant (more effect for more money) and the remaining 38% in the north-west quadrant (less effect for more money). Figure 5 (reporting the CEAC based on QALYs) shows that, with a ceiling ratio of €20,000, the probability that the intervention would be cost effective was 46%.

Sensitivity analysis with alternative scenario

After evaluation by the multidisciplinary expert team, 29 patients were referred to secondary care. In the alternative scenario, in which patients were referred only for the reasons stipulated in the Dutch Guidelines for General Practitioners, 18 of the patients would not have been referred to secondary care. This resulted in lower costs (in the CEA €280 on average per patient instead of €417), which led to an ICER of €3,072 (95% CI: -10,778 to 22,440) and an ICUR of €22,195 (95% CI: -83,712 to 74,386).

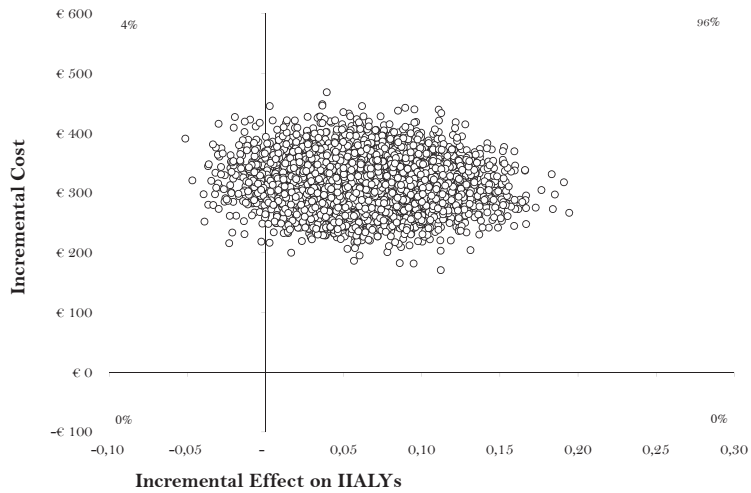

Figure 2 Incremental cost-effectiveness plane for IIALYs: 5000 bootstrap replications for the mean difference between costs and IIALYs.

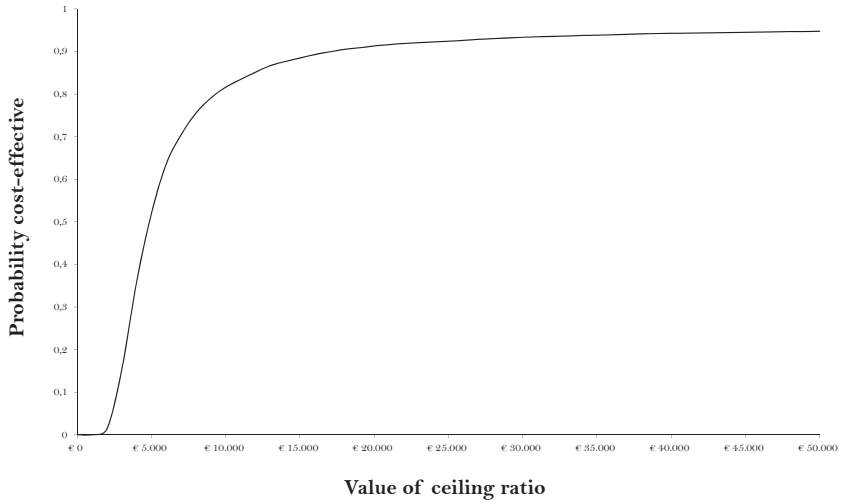

Figure 3 Cost-effectiveness acceptability curve for IIALYs.

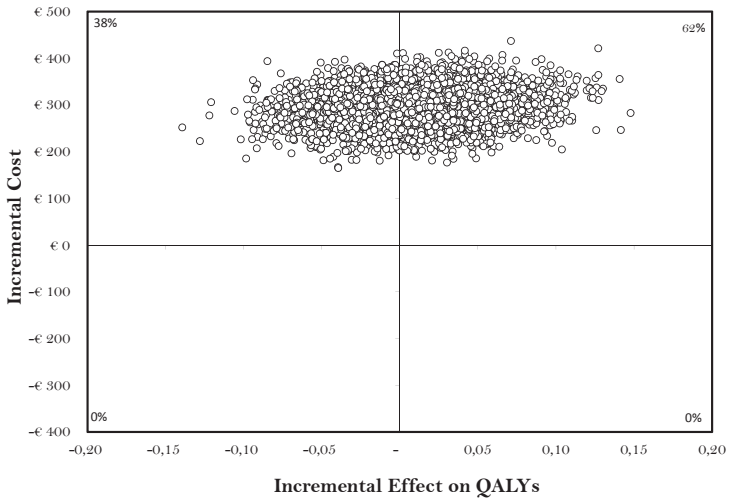

Figure 4 Incremental cost-effectiveness plane for QALYs: 5000 bootstrap replications for the mean difference between costs and QALYs.

DISCUSSION

Main findings

Actively encouraging older women with urinary incontinence to undergo diagnostic testing and treatment leads to relevant health gains against reasonable costs: to gain one extra year in a perfect health state with regard to urinary incontinence, €5,179 needs to be invested; to gain one year in a perfect health state, €23,907 needs to be invested. In the alternative and more realistic scenario in terms of implementa-

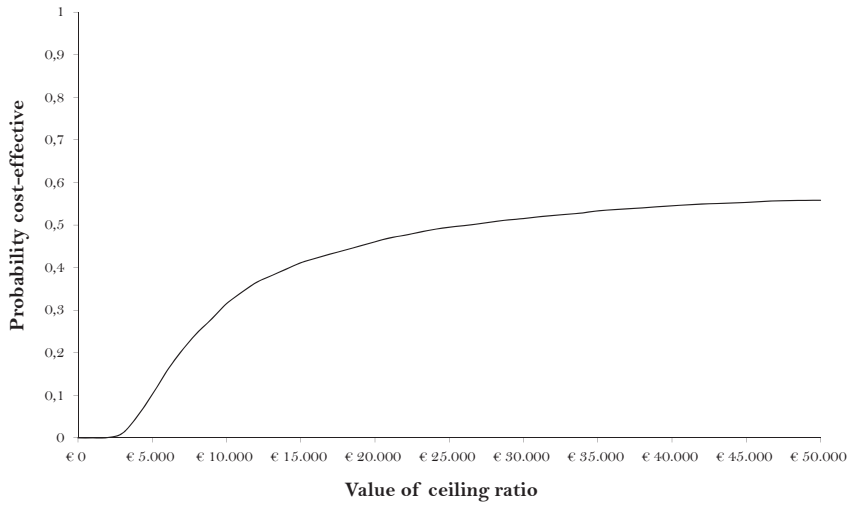

Figure 5 Cost-effectiveness acceptability curve for QALYs.

tion, in which costs resulting from unnecessary consultations in secondary care were removed, these amounts were €3,072 and €22,195, respectively.

Studies with CEAs of conservative treatment options for urinary incontinence in primary care are very scarce[32]. Most previous CEAs in this field used general quality of life outcomes. For example, in a prospective observational study, Mihaylova et al. compared duloxetine with any conservative treatment for stress urinary incontinence among women with an average age of 56 years[33]. Follow-up period was 12 months. They found that patients who received conservative treatment did not have a health gain in terms of QALYs as compared with no treatment, and did not have a significant impact on costs. The ICER based on QALYs ranged from £2,970 (€3,547) to £6,379 (€7,618), depending on the analysis method used. This is much lower than the €23,907 we found, implying that pelvic floor muscle training is less likely to be cost-effective than conservative treatment in general. However, since this result is based on observational data, its actual value remains questionable. In general, there is a need for studies in which a CEA is performed in parallel with a randomized controlled trial[32].

However, since generic quality of life scores may lack responsiveness for changes in quality of life of incontinent women, we developed a new score in order to calculate a disease-specific quality of life score at the patient level: the IIALY. This score allowed us to calculate the amount of money needed to be invested for one extra year in a perfect health state. This IIALY score was derived from the impact on quality of life score of the ICIQ questionnaire[13].

In a study by Albers et al., investigating the effect of involving nurse specialists for urinary incontinence in primary care, a condition quality of life score was also used,

derived from the ICIQ: the Incontinence Severity weighted Life Years (ISLY) score[29]. They used the sum score of the ICIQ (instead of the impact score that we used), thereby including the severity and type of symptoms in the score. Albers et al. found an ICER of €11,536 (costs per gained ISLY), which is more than two times higher than our ICER of €5.179 (costs per gained IIALY). This difference is mainly due to the 4 times lower clinical effect in the study of Albers et al., due to an unexpected improvement in the control group[34]. They assumed that this might be caused by a changed care-as-usual policy of the participating GPs.

This is a relevant problem in randomized controlled trials, referred to as 'contamination': participants or physicians in the control group might 'learn' from the intervention that is offered in the intervention group, resulting in a higher than expected effect size in the control group. We tried to avoid this threat of contamination by performing cluster randomization[35]. In this way, participants in both groups were separated from each other.

Indirect non-medical costs of urinary incontinence (e.g. costs of washing and laundry, and clothing expenses) were not taken into account in the current CEA in order to avoid excessively long questionnaires for the participants[36]. To get a realistic view of the actual costs resulting from urinary incontinence, registration of these indirect non-medical costs is recommended[4]. However, in the setting of the URINO trial it was acceptable to register only direct costs and this probably only led to a slight underestimation of the effect of the intervention on costs.

Utility was reflected by changes on the EuroQol-5 Dimensions (EQ5D) scores, valued by the Dutch EQ5D tariff[17,28]. We decided to use the Dutch tariff instead of the more frequently used British tariff, because valuation of health status may be culturally specific. Differences between these two latter tariffs are minimal; the choice for a specific tariff is not likely to affect our conclusions, whilst it enhances comparability with other Dutch CEAs in this field.

Implications and further research

We conclude that the positive clinical effect of actively encouraging older women with urinary incontinence to undergo diagnostic testing and treatment can be achieved against reasonable costs, with an improvement of symptom-specific quality-adjusted life-years. Patients and society could benefit from such a proactive approach of GPs towards older women with urinary incontinence. This approach is likely to reduce the impact of urinary incontinence on patients' quality of life and, assuming that a decision-maker is willing to pay €20,000 for this gain in health, the probability that this intervention will be cost-effective reaches 1.

Based on these findings, if a patient at risk for urinary incontinence consults her GP, we recommend that the GP should ask about symptoms and, with a positive

response, diagnostic testing and treatment should be offered. However, additional further studies are needed to establish the best way to implement our proposed strategy. In addition, it is recommended to perform further research on the effect and cost-effectiveness of systematic screening of the open population on urinary incontinence[11].

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CHAPTER 5

Systematic screening for urinary incontinence in older women: who could benefit from it?

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Scandinavian Journal of Primary Health Care, 2012; 30: 21-28

ABSTRACT

Objective

To identify women who are suffering from urinary incontinence but do not consult a physician and to identify reasons for this.

Design

Survey study as part of a randomized controlled trial that investigates the effects of a standardized assessment and evidence-based treatment on urinary incontinence in older women, the URINO project.

Setting

Female patients from general practices in the Northern part of the Netherlands.

Patients

A total of 225 women of 55 years and older suffering from urinary incontinence

Main outcome measures

Number of patients with urinary incontinence who are not registered by their GP as suffering from this, factors associated with help-seeking behaviour, and reasons for not seeking help.

Results

Of the 225 patients, 143 (64%) were not registered by their GP as suffering from urinary incontinence.

These women were more often younger and had lower levels of distress due to their urogynaecological symptoms. The most common reason for not consulting a GP was that patients considered their symptoms not to be serious enough.

Conclusion

The prevalence of older women with urinary incontinence who do not seek help is high. Help-seeking behaviour is associated with increasing age and higher levels of distress caused by the symptoms. Younger patients more often hesitate to consult their GP if they perceive their symptoms to be relatively mild.

INTRODUCTION

Urinary incontinence is a very common health problem among older women: about one in three women suffers from it[1]. Though it is not a life-threatening condition, it can affect quality of life adversely. It may lead to social isolation, lack of self-confidence, shame, and feelings of depression[2-4]. Effective treatment options, such as pelvic floor physiotherapy, bladder training, and anticholinergic drugs, are available but underused, because only a minority of the affected patients seek help[5, 6]. The main reasons for not seeking help are that the urinary incontinence is seen as a problem that must be self-managed and that it is a normal sequel of ageing which should be accepted[6-8]. Severity of the incontinence and a high impact of the symptoms on quality of life are identified as factors associated with seeking help[6, 8-11].

The literature is equivocal regarding the role of age in help-seeking behaviour in urinary incontinence. Some authors found that older women are more likely to seek help than younger women, whereas others conclude the opposite[7, 9, 10]. Some factors potentially related to help-seeking behaviour have not been studied at all, for instance gender of the general practitioner (GP), frequency of contact with the GP, and comorbidity.

The aims of this study were to identify women who do not consult a professional for their incontinence symptoms, and to determine factors related to not seeking help and reasons for not seeking help.

MATERIAL AND METHODS

Design

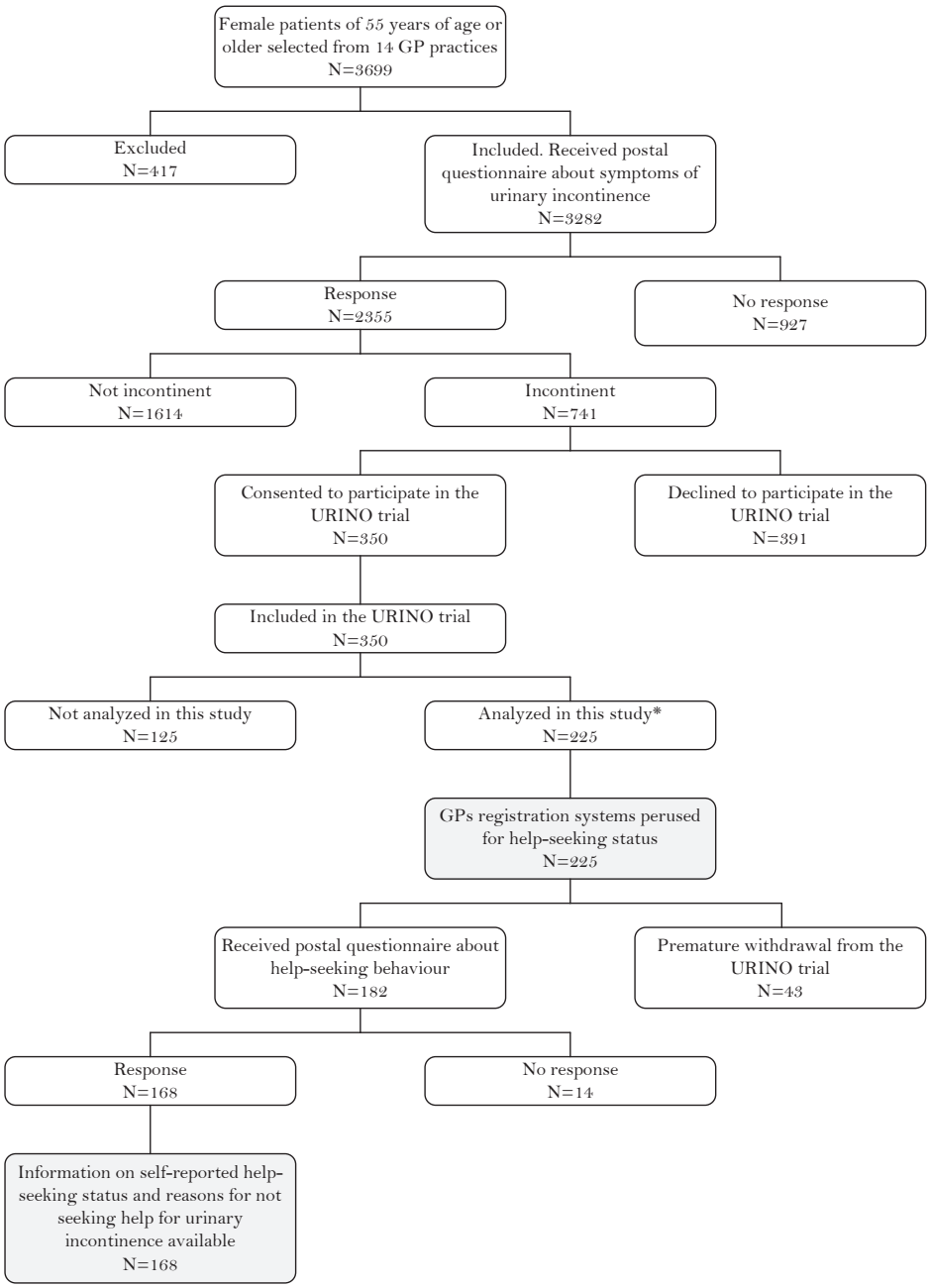
This survey study is part of the URINO project, a randomized controlled trial that investigates the effects of a standardized assessment and evidence based treatment on urinary incontinence in older women.

Setting

The URINO project was conducted in 14 general practices in the northern part of the Netherlands and started in January 2008. In the Netherlands, the GP is a gatekeeper: patients may consult a medical specialist only after obtaining a referral from their GP.

Patients

All female patients of 55 years and older were asked by their GP to complete a screening questionnaire on the presence of symptoms of urinary incontinence. Uri-



* The first 225 participants of the URINO-project.

Figure 1 The study population

nary incontinence was defined as involuntary leakage of urine once a month or more. Patients who reported urinary incontinence were invited to participate in the trial. They were included after they provided informed consent. For this study, data from the first 225 consecutive participants of the URINO project were analysed (Figure 1).

Data collection

Data were derived from the GPs ' registration files and the baseline assessment of the URINO project. The GPs ' registration files were used to obtain information on whether the patients were known by their GP as suffering from urinary incontinence, their consultation behaviour in the three months preceding the inclusion, use of medication for chronic diseases, and comorbidity (the weighted Charlson Index)[12].

From the baseline measurement of the URINO project information was obtained on age, education level, and sexual activity. Also several validated questionnaires were used: the ICIQ-UI SF (Incontinence Consultation on Incontinence Questionnaire, which measures symptoms and impact of urinary incontinence), the ISI (Incontinence Severity Index, consisting of two questions regarding frequency and amount of leakage), UDI (Urogenital Distress Inventory) combined with the IIQ (Incontinence Impact Questionnaire) (which both measure health-related quality of life in multiple domains), EQ5D (EuroQol 5 Dimensions, for measuring general quality of life), and the GARS (Groningen Activity Restriction Scale, a two-domain questionnaire regarding functional status)[13-22].

For this survey, a questionnaire on help-seeking behaviour was developed. Patients were asked if they had consulted their GP for urinary incontinence. If a patient had not visited her GP for urinary incontinence, she was invited to explain her decision not to consult her GP for this problem (open question). Subsequently, she was asked to mark one or more of the reasons that are mentioned in Table III, a list of items derived from the literature[6, 7, 9].

Statistical analysis

A multi-level analysis was conducted to address the factors related to help-seeking behaviour. In our data, individual patients (level 1) were nested within practices (level 2). Initially, univariate multi-level analysis was performed to determine the ORs of the several patient characteristics. Variables that showed a significant association in the univariate analysis were fitted in a subsequent multivariate multi-level logistic regression model. A best subset stepwise forward procedure was followed to develop a prediction model for not seeking help.

Information derived from the questionnaires was analysed with descriptive statistics. To identify women who did not seek help, the three most frequent reported reasons for not seeking help were identified and analysed in the same way as described

for the help-seeking behaviour: initially the potential predictive factors were tested univariately and only a significant association between a factor and the outcome "seek help" led to fitting that variable in the multivariate model. Data were analysed by using SPSS 16.0 and MLwiN 2.19. A p-value of 0.05 was considered statistically significant.

Table 1 Baseline characteristics of the study population (known and unknown by the GP with urinary incontinence)

	known (n=82)	not known (n=143)
Age at baseline in years; mean (SD)	69.39 (9.57)	63.81 (7.24)
Education level		
Low; n (%)	29 (35.4)	31 (21.8)
Average; n (%)	35 (42.7)	64 (45.1)
High; n (%)	18 (22.0)	47 (33.1)
Difference in age between patient and GP; mean (SD)	23.2 (11.1)	18.2 (11.5)
Male GP; n (%)	56 (68.3)	70 (49.0)
Location practice rural; n (%)	55 (67.1)	81 (56.6)
Self-reported type of incontinence		
Stress incontinence; n (%)	11 (14.7)	48 (36.6)
Urge incontinence; n (%)	20 (26.7)	20 (15.3)
Mixed incontinence; n (%)	44 (58.7)	63 (48.1)
Severity of the incontinence according to the ISI score*		
Slight; n (%)	12 (16.0)	43 (32.3)
Moderate; n (%)	33 (44.0)	68 (51.1)
Severe and very severe; n (%)	30 (40.0)	22 (16.5)
Urinary incontinence during sexual intercourse; n (%)	9 (31.0)	14 (21.5)
Number of medications for chronic diseases; median (IQR)	2 (0- 5)	1 (0- 3)
Total number of consultations; median (IQR)	11 (7-19)	9 (4-16)
Number of home visits; median (IQR)	0 (0- 1)	0 (0- 0)
Charlson index for co-morbidity; median (IQR)	0 (0- 1)	0 (0- 1)
UDI score for distress caused by urogynaecological symptoms; median (IQR)*	15.9 (8.0-28.0)	9.6 (6.9-15.1)
IIQ score for psychological impact of urinary incontinence; median (IQR)*	0.0 (0.0- 4.8)	0.0 (0.0- 0.0)
EQ5D score for health outcome and utilities; median (IQR)*	0.8 (0.7- 0.9)	0.8 (0.8- 1.0)
GARS score for functional status; median (IQR)*	20.0 (18.0-24.0)	18.0 (18.0-21.0)

*ISI: Incontinence Severity Index; UDI: Urogenital Distress Inventory; IIQ: Incontinence Impact Questionnaire; EQ5D: EuroQol 5 Dimension; GARS: Groningen Activity Restriction Scale

RESULTS

Patient characteristics

Of the 225 participants, 143 (64%, 95% CI 57.3 – 69.9) were not registered by their GP as suffering from urinary incontinence. The mean age of these women was 63.81 (SD 7.24), whereas among women with known urinary incontinence the mean age was 69.93 (SD 9.57) (Table 1). The women with known urinary incontinence more often had a male GP in a rural practice area; the women who were not known more often had a female GP and were living in an urban area.

Table 2 Factors related to not seeking help for urinary incontinence

		univariate multilevel analysis		multivariate multilevel analysis	
		OR (95%-CI)	p	OR (95%-CI)	p
*	Age at baseline	0.93 (0.89- 0.96)	<0.01	0.91 (0.87-0.96)	<0.01
	UDI score for distress caused by urogynaecological symptoms§	0.95 (0.92- 0.98)	<0.01	0.95 (0.92-0.98)	<0.01
†	Age patient minus age GP	0.94 (0.91- 0.97)	<0.01		
	Education level				
	Low	1			
	Average	1.66 (0.84- 3.26)	0.14		
	High	2.50 (1.16- 5.37)	0.02		
	Gender GP				
	Male	1			
	Female	2.25 (1.27- 3.97)	0.01		
	Self-reported type of incontinence				
	Stress incontinence	1			
	Urge incontinence	0.24 (0.10-0.60)	<0.01		
	Mixed incontinence	0.34 (0.16-0.72)	<0.01		
	Number of prolonged medications	0.88 (0.80- 0.98)	0.01		
	Total consultations	0.96 (0.94- 0.99)	0.01		
	IIQ score for psychological impact of urinary incontinence §	0.95 (0.91- 0.99)	0.01		
	EQ5D score for health outcome and utilities §	4.34 (1.02-18.42)	0.05		
	GARS score for functional status §	0.92 (0.87- 0.97)	<0.01		
‡	Severity of incontinence according to the ISI score §				
	Slight	1			
	Moderate	0.64 (0.29-1.38)	0.25		
	Severe and very severe	0.22 (0.09-0.51)	<0.01		

* variables included in the multivariate multilevel model; † variables removed from the multivariate multilevel model; ‡ variables not included in the multivariate multilevel analysis; § UDI: Urogenital Distress Inventory; IIQ: Incontinence Impact Questionnaire; EQ5D: EuroQol 5 Dimension; GARS: Groningen Activity Restriction Score; ISI: Incontinence Severity Index

Factors associated with help-seeking behaviour

A younger age of the patient (OR 0.91; 95% CI 0.87 – 0.96) and lower levels of distress due to the urogynaecological symptoms (UDI score OR 0.95; 95% CI 0.92 – 0.98) proved to be significant predictors for not being known by the GP as suffering from urinary incontinence (Table 2).

Reasons for not seeking help

The most frequently mentioned reason for not consulting the GP for urinary incontinence was that the symptoms were not severe enough (n= 105, 73.4%) (Table 3). Severity of the incontinence (moderate: OR 0.14; 95% CI 0.03 – 0.72 and (very) severe: OR 0.14; 95% CI 0.02 – 0.81) and distress from the incontinence symptoms (UDI score OR 0.93; 95% CI 0.88 – 0.98) were associated with this reason for not seeking help (Table 4).

The second most frequently mentioned reason was that women had found a way to cope with their symptoms of incontinence (n=82, 57.3%). These women more often had an older GP (OR 1.09; 95% CI 1.02 –1.15) and more often experienced urinary incontinence during sexual intercourse (OR 5.22; 95% CI 1.15 – 23.60) as compared with women reporting other reasons, although the last result must be interpreted with caution because of the relatively high number of missing values concerning the intercourse variable.

Table 3 Reasons for not consulting the general practitioner for urinary incontinence

	Total (n=143)
I think my involuntary loss of urine is not severe enough to consult my general practitioner; n (%)	105 (73.4)
I have found a way to cope with it; n (%)	82 (57.3)
I think involuntary loss or urine is a normal sequel of ageing; n (%)	67 (46.9)
I think that there is no cure for my involuntary loss of urine; n (%)	34 (23.8)
My general practitioner didn't ask me about involuntary loss of urine; n (%)	29 (20.3)
I have other health problems which take priority; n (%)	15 (10.5)
I feel uncomfortable to inconvenience my general practitioner with involuntary loss of urine; n (%)	17 (11.9)
I think my general practitioner would ignore my involuntary loss of urine; n (%)	17 (11.9)
I am embarrassed to discuss involuntary loss of urine with my general practitioner; n (%)	7 (4.9)
I think that the treatment options for involuntary loss of urine are too demanding on me; n (%)	7 (4.9)
I think that my involuntary loss of urine a transitory problem; n (%)	5 (3.5)

Considering urinary incontinence as a normal sequel of ageing was reported by 67 women (46.9%); these women were more often older (OR 1.07; 95% CI 1.02 – 1.11) than the women who did not give that reason. Their GP practice was less often located at a rural region (OR 0.38; 95% CI 0.15 – 0.96).

Table 4 Factors related to the top 3 reasons for not seeking help

		Urinary incontinence is not severe enough	
		OR (95%CI)	p-value
*	Severity of incontinence according to the ISI score ‡		
	Slight	1	
	Moderate	0.14 (0.03- 0.72)	0.02
	Severe and very severe	0.14 (0.02- 0.81)	0.03
	UDI score for distress caused by urogynaecological symptoms ‡	0.93 (0.88- 0.98)	0.01
†	Age at baseline		
	Charlson index for co-morbidity		
	Home visits		
	IIQ score for psychological impact of urinary incontinence ‡		
	Education level		
	Age GP at baseline		
		I have found a way to cope with it	
		OR (95%CI)	p-value
*	Age GP at baseline	1.09 (1.02- 1.15)	0.01
	Urinary incontinence during sexual intercourse	5.22 (1.15-23.60)	0.03
†	Self-reported type of incontinence		
		Urinary incontinence is normal sequel of ageing	
		OR (95%CI)	p-value
*	Age at baseline	1.07 (1.02- 1.11)	0.01
	Location practice		
	urban	1	
	rural	0.38 (0.15- 0.96)	0.04
†	Self-reported type of incontinence		

* variables included in the multivariate multilevel model; † variables removed from the multivariate multilevel model; ‡ ISI: Incontinence Severity Index; UDI: Urogenital Distress Inventory; IIQ: Incontinence Impact Questionnaire

The fourth most mentioned reason for not seeking help was "I think there is no cure".

DISCUSSION

Principal findings

Help-seeking behaviour of older women in primary care with urinary incontinence was studied in women of 55 years and older who were participating in a RCT. In total, 64% (95% CI: 57.3 – 69.9) of the participating patients with urinary incontinence were not known by their GP as suffering from this problem. These women were younger and had relatively low levels of distress. Although GP characteristics such as age,

gender, and urbanization grade showed an association with help-seeking behaviour in the univariate analyses, in the final multivariate analysis these variables disappeared from the model. The main reason given for not seeking help was: "The symptoms are not severe enough".

Strengths and limitations

Although help-seeking behaviour of women with urinary incontinence has been frequently studied, we found that to the best of our knowledge this is the first study that matches information from the patient with the GPs ' registration systems. This could lead to new insights, because it uses information both from a doctor's perspective ("Urinary incontinence should be the main reason for consultation") and from a patient's perspective ("I have raised this problem").

A possible limitation of this study is that the study population is not a random sample of the total population of older women with urinary incontinence, since it included women willing to participate in a trial. However, with a response rate of 72% on the screening questionnaire (2355 out of 3282 forms were returned) and 92% on the questionnaire about help-seeking behaviour (168 out of 182), we are confident that our data are robust.

Comparison with existing literature

In this study, we found that 64% (95%-CI 57.3 – 69.9) of the women had never discussed their problem of urinary incontinence with their GP. Peters et al. found a prevalence of undiagnosed urinary incontinence in women of 65 years and older of 86% (95% CI: 80.7 –90.6), while Dugan et al. found a prevalence of 70% (95% CI: 62.4 – 78.2) in women of 60 years and older[8,9]. An explanation for these varying prevalences might be that the definition of urinary incontinence in studies differs, especially concerning the time-period in which symptoms occurred, as well as the definition of help-seeking behaviour, the way women were recruited, and the age categories of the study populations.

Although not new – it has been reported by others – it is still puzzling that women as they become older are more likely to be known by their GP as having urinary incontinence. A good explanation has not been found so far[9, 23-25]. It could be explained by an unidentified interaction effect with age, like severity of the incontinence. However, no evidence of such interaction was present in our final regression model. Another explanation could be that a GP has a higher index of suspicion of urinary incontinence in older women and as a consequence may ask more frequently for symptoms.

Less unexpected is our finding that women with relatively low levels of distress due to their symptoms are less likely to seek help. This corresponds with the results of previous studies[6, 7, 9].

In our study, the most frequently reported reason for not seeking help for urinary incontinence was that the symptoms were considered not severe enough. Teunissen et al. reported the same finding[11]. That urinary incontinence is a normal sequel of ageing was reported by almost half of the patients as a reason for not seeking help. Commercials about absorbent products, in which remarkably happy older women experience virtually no discomfort from urinary incontinence, are not contributing to a change in the perception of this problem. It is surprising that a quarter of our study population assumed that urinary incontinence cannot be cured. This means that informing women that urinary incontinence can be treated effectively is still very important.

Implications of the study and future research

In this study, the most common reason for not consulting a GP was that patients considered their symptoms not to be severe enough. This knowledge may be useful. Information campaigns about urinary incontinence, initiated from the general practice or publicly funded, might make patients more aware about this problem and the available good treatment options, even when their symptoms are relatively mild.

This study also demonstrates that women who do not seek help for urinary incontinence are relatively young with lower levels of distress. As a consequence, GPs should be more attentive to the presence of urinary incontinence in relatively young women, as this group may not easily consult a GP for incontinence but could benefit from treatment, and also to prevent further deterioration of symptoms. Perhaps all women above 55 years should be systematically screened for urinary incontinence, as already suggested by Rohr et al[26]. The effectiveness of a proactive approach towards older women, for example by using a single question intended to gather information on the presence of urinary incontinence during routine medical check-ups of elderly women in general practice, should be subject to further investigation. In this study we describe the characteristics of the women who hesitate to seek help. An intervention study that has already started will have to show which women will profit from treatment of their incontinence and should be encouraged to seek help.

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CHAPTER 6

Severity, not type, is the main predictor of decreased quality of life in elderly women with urinary incontinence: a population-based study as part of a randomized controlled trial in primary care

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Health and Quality of Life Outcomes 2012;10:153.

ABSTRACT

Background

Urinary incontinence negatively influences the lives of 25-50% of elderly women, mostly due to feelings of shame and being limited in activities and social interactions. This study explores whether differences exist between types of urinary incontinence (stress, urgency or mixed) and severity of the symptoms, with regard to their effects on generic and condition-specific quality of life.

Methods

This is a cross-sectional study among participants of a randomized controlled trial in primary care. A total of 225 women (aged ≥ 55 years) completed a questionnaire (on physical/emotional impact and limitations) and were interviewed for demographic characteristics and co-morbidity. Least squares regression analyses were conducted to estimate differences between types and severity of urinary incontinence with regard to their effect on quality of life.

Results

Most patients reported mixed urinary incontinence (50.7%) and a moderate severity of symptoms (48.9%). Stress urinary incontinence had a lower impact on the emotional domain of condition-specific quality of life compared with mixed urinary incontinence (r = −7.81). There were no significant associations between the types of urinary incontinence and generic quality of life. Severe symptoms affected both the generic (r = −0.10) and condition-specific (r = 17.17) quality of life.

Conclusions

The effects on condition-specific quality of life domains differ slightly between the types of

incontinence. The level of severity affects both generic and condition-specific quality of life, indicating that it is not the type but rather the severity of urinary incontinence that is the main predictor of decreased quality of life.

BACKGROUND

Urinary incontinence is a common condition in women. About 25% of women of reproductive age and up to 50% of postmenopausal women are troubled by this condition[1]. The International Continence Society defines urinary incontinence as 'a complaint of any involuntary leakage of urine'[2]. This leakage can be subdivided into three main categories: stress urinary incontinence (urinary incontinence on effort or exertion, sneezing or coughing), urgency urinary incontinence (urinary incontinence immediately preceded by urgency), and mixed urinary incontinence (both stress and urgency symptoms)[2]. Other types of incontinence, like overflow, functional, situational and nocturnal, or incontinence dependent on neurologic conditions or fistulas, are less common and are not a part of this study[2].

Whilst stress incontinence is engendered by urethral hypermobility or sphincter weakness, urgency incontinence is often caused by detrusor overactivity[3]. Besides the variation in type and cause, the levels in severity of urinary incontinence range from slight to very severe[4].

The consequences of urinary incontinence may be considerable, often causing embarrassment, stress, frustration, loss of dignity, depressive feelings and limitations in activities because of (fear of) leakage of urine[5, 6]. Urinary incontinence not only has a negative effect on a woman's physical and sexual life, but may also impede her social interactions due to insecurity about her own hygiene[3].

Because the burden of urinary incontinence differs between individuals, measurement of symptoms alone is insufficient to gain a realistic impression of this burden[7]. The burden of incontinence can depend, for instance, on the degree of acceptance and adjusting to the condition and/or on co-morbidity, the consequences of which might be considered even more burdensome[8]. A patient's perception of her urinary incontinence, i.e. the importance that she attaches to her symptoms, also has a considerable influence on whether or not to seek help. Generally, the effect of treatment is measured by clinical observations (e.g. a change in symptoms) and by urodynamic tests. However, assessing the burden of the condition from a patient's perspective and the impact on her quality of life is also an important part of care and treatment[9, 10].

The quality of life of patients with urinary incontinence is often established with either generic instruments or with condition-specific ones. A condition-specific measurement of urinary incontinence is supposed to more specifically assess the aspects of quality of life that are impaired by urinary incontinence. Generic scales are designed to compare the effects of general health on quality of life on several (e.g. physical and social) dimensions, but may be insensitive to the influence of urinary incontinence on specific aspects of quality of life[11, 12]. Thus, both these measuring instruments are associated with (the amount of) urine loss, but to a differing extent[13, 14].

In addition to the variety in measuring instruments there is also diversity in study outcomes.

Studies on the effects of the three types of urinary incontinence on quality of life suggest that women with mixed and urgency urinary incontinence tend to experience a greater impact on quality of life than women with stress urinary incontinence[15, 16]. The severity of incontinence is also supposed to influence the quality of life[17].

Therefore, the aim of the present study is to compare the effects of different types and levels of severity of urinary incontinence on quality of life, using both generic and condition-specific questionnaires.

METHODS

Design

This cross-sectional study used data from the URINO project (which started in 2008) and examines the effect and cost-effectiveness of a diagnostic protocol and treatment of urinary incontinence in older women in primary care, compared to standard care[18]. The URINO project is a cluster randomized controlled trial in which the patients' general practitioners (GPs) serve as the clusters; the patients were randomized into an intervention group and a control group.

All participants received a screening questionnaire and, if troubled by involuntary leakage at least once a month and willing to participate, were interviewed and completed a baseline questionnaire. For the present study, baseline data from the intervention group and the control group were used. Patients in the intervention group also underwent a gynecological examination and some additional tests; however, since these outcomes are irrelevant for the present study they are not further discussed here.

The URINO project was approved by the Medical Ethical Committee of the University of Groningen.

Study population

The source population consisted of 3,684 women aged ≥ 55 years who were registered in 14 general practices in the northern part of the Netherlands. These women were known by their GP to either have or not have urinary incontinence. Of the total group, 399 women were excluded (and received no screening questionnaire) for the following reasons: currently treated for a urogynecological condition (during the previous year), had an indwelling catheter, had overflow incontinence, were suffering from malignancies, were severely demented, or were in a poor physical condition (according to their GP). The remaining women (n=3,285) received a short postal

screening questionnaire on symptoms of urinary incontinence and on their willingness to participate.

The response rate was 73% (n=2,390) and, of this group, 31% (n=744) suffered from urinary incontinence (defined as involuntary leakage of urine once a month or more). Of these women with urinary incontinence, 48% (n=357) was willing to participate. Patients were then included if they were able to fill in questionnaires in Dutch and if they signed informed consent. Finally, an additional 7 women were excluded because of illiteracy or inability to complete a bladder diary, leaving a total of 350 women who provided informed consent and completed the baseline measurements.

For the present study, of the 350 available women only the first 225 participating women were included. The reason for this is that, for these 225 patients (recruited from the first general practices taking part in the main URINO study), additional detailed information on comorbidity was available from the GPs' registration systems.

Measurements

Some data were collected by means of an interview and a self-administered questionnaire, whereas data on age and postal code were already known at the time of screening. After completion, participants brought their self-administered questionnaires to the center and two researchers (one per group) interviewed them, using a standardized list of questions requiring factual answers.

Besides the patient's clinical history, the interview also covered demographic characteristics such as education level, socioeconomic status (SES) and marital status.

Both education and SES were operationalized into three levels: low, medium (called average in the case of SES) and high. The education levels are described in Table 1. For SES, participants were classified according to the postal code of the area in which they lived. These SES classes were grouped by income, employment and education (according to the Netherlands Institute for Social Research, 2006).

The weight and height of participants were measured to calculate body mass index (BMI).

The self-administered questionnaires comprised questions on the frequency and amount of involuntary loss of urine, assessed by the Incontinence Severity Index (ISI)[4]; this is measured on a 12-point scale by multiplying the frequency of losing urine (once a month, couple of times monthly, couple of times weekly or every day or night) and severity (losing drops, puddles or more). Further information on the symptoms of urinary incontinence was measured by the Urinary Distress Inventory (UDI) and the International Consultation Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI-SF)[19]. The answers to the questionnaires were used to establish the (self-reported) type of urinary incontinence.

Stress urinary incontinence was assumed to be present when patients gave one of the following answers to the question 'When do you lose urine?' from the ICIQ-UISF: 'I lose urine during physical activity' or 'I loss urine when I cough or sneeze'. Women who answered this same question with 'I lose urine before I can reach the toilet' or who confirmed one question from the UDI, i.e. that they lost urine with the urgency to urinate ('Do you have involuntary leakage of urine when you feel the urgency to urinate?') were assumed to suffer from urgency incontinence. Both symptoms refer to mixed urinary incontinence.

The generic quality of life was assessed by a questionnaire on health outcome and utilities, i.e. the Euroqol 5D (EQ-5D). The EQ-5D is designed to complement other quality of life measurements (such as condition-specific ones) and consists of five questions on different aspects of health: mobility, self-care, usual activities, pain, and psychological status. The score depends on the person's own judgment regarding health status and ranges from −0.33 (serious problems with the mentioned aspects) to 1 (no problems at all)[20, 21].

The condition-specific quality of life, similar to the influence of urinary incontinence on (social) activities and wellbeing, was measured with the Incontinence Impact Questionnaire (IIQ-7). Scores on the IIQ-7 range from 0–100, where 0 indicates no impact and 100 indicates very high impact of urinary incontinence on four domains, i.e. physical activity, social relationships, travelling and emotional health[22]. Scores on the four subdomains are obtained on an ordinal range (0, 16.67, 33.33, 50.00, 66.67, 83.33 and 100) and their sum is the IIQ-7 total score (range 0–400).

Data on co-morbidity were withdrawn from the registration systems of the GPs, according to the Charlson index, which predicts the one-year mortality for patients with a range of co-morbid conditions (taking into account both the number and severity of conditions)[23-25].

Analysis

Primary outcome of this study was the condition-specific quality of life, as measured by the IIQ-7 and the secondary outcome was the generic quality of life as defined by the score on the EQ-5D. Determinants were the self-reported types of urinary incontinence and the severity of the symptoms, measured by the ICIQ-UI-SF, and by one question from the UDI and the ISI, respectively.

First, the patient characteristics at baseline (age, BMI, SES, marital status, education) and co-morbidity were described, as well as the self-reported type and severity of urinary incontinence. Next, correlations were calculated between all possible confounding variables as mentioned above and the outcome variables (the EQ-5D and IIQ-7), using Spearman's correlation test. A high score on the EQ-5D indicates a

higher quality of life, whereas a high score on the IIQ-7 indicates a large impact and therefore a diminished quality of life.

Finally, associations between the types and severity of urinary incontinence and the outcome variables were assessed. The categories severe and very severe urinary incontinence were taken together due to the small number of patients reporting very severe symptoms. Multilevel analysis was performed to take into account dependency in the data between patients with the same GP.

The dependent structure between patients and GPs as measured by the residual ICC was low (ρ=0.004), therefore an ordinary least squares (OLS) regression analysis was performed. Regarding the outcome variable EQ-5D, no indication for violating the assumptions of the OLS regression analysis was found. However, violation of the normality assumption was found for the IIQ-7. As ordinal and logistic regression analysis yielded the same conclusions, only the results of the OLS regression analyses are reported.

Scores on the IIQ-7 were missing for 14 patients. Furthermore, an additional 49 patients had a missing score on marital status. Five other patients had missing data for type of urinary incontinence and two other patients had missing data for severity of urinary incontinence; this resulted in a total of 155 patients available for analysis of the IIQ-7 scores.

For EQ-5D, the score was not available for 6 patients. Also, for an additional 51 patients no data were available on marital status. Five other patients had missing data for type of urinary incontinence and another patient had a missing value for severity of urinary incontinence; this resulted in a total of 162 patients available for analysis of the EQ-5D.

All data were analyzed using SPSS version 17.

RESULTS

The baseline characteristics of the study population and their self-reported types and severity of urinary incontinence are presented in Table 1. Of the 225 respondents, the minimum age at the moment of screening was 55 years, mean age was 65.4 (SD=9.57) years.

Whereas the majority reported mixed urinary incontinence (50.7%), the participants were also troubled with stress (28.4%) and urgency (17.8%) incontinence. Regarding the degree of severity of complaints, for 48.9% it was moderate, for 26.2% it was slight, for 19.1% it was severe, and 3.6% of the women reported very severe complaints.

Table 1 Characteristics of the study population of female patients aged 55 years and older with urinary incontinence (n =225)

		n (%) or mean ± SD
Age (years)		65.4 ± 9.57
BMI		27.6 ± 5.2
Charlson index [a]	Value 0 - 1	193 (55.4)
	Value 2 - 3	30 (8.6)
	Value 6	2 (0.6)
Education [b]	Low	59 (26.2)
	Medium	101 (44.9)
	High	64 (28.4)
	Unknown	1 (0.4)
Social economic status score [c]	Low	44 (19.6)
	Average	167 (74.2)
	High	14 (6.2)
Marital status	No partner	56 (24.9)
	Partner	115 (51.1)
	Unknown	54 (24.0)
Self-reported type of urinary incontinence	Stress incontinence	64 (28.4)
	Urgency incontinence	40 (17.8)
	Mixed incontinence	114 (50.7)
	Unknown	7 (3.1)
Severity of urinary incontinence according to the ISI	Slight	59 (26.2)
	Moderate	110 (48.9)
	Severe	43 (19.1)
	Very severe	8 (3.6)
	Unknown	5 (2.2)

[a] Charlson index: weighted risk of mortality < 1 year, dependent on co-morbidity (score 6 as the highest risk).
[b] Low: primary/ junior secondary vocational education; medium: secondary/ senior vocational/ higher secondary education; high: higher professional/ university education.
[c] Dependent of income, employment and educational according to the postal code of the area the participants live in (by the Netherlands Institute for Social Research, SCP 2006).

Table 2 shows that age is weakly and negatively related to the primary outcome EQ-5D. BMI also has a weak negative correlation with the EQ-5D, but is weakly and positively related to the IIQ social domain. SES correlates weakly and negatively with the IIQ physical activity and the emotional health domain, as well as with the total IIQ-7 score. There is a moderate and negative correlation between co-morbidity and the EQ-5D, and education is weakly and negatively associated with both the IIQ physical and social domain, whereas marital status has a weak and positive relationship with the IIQ social domain.

Table 2 Spearman's correlations between patient characteristics and quality of life

	Age	BMI	SES a	Marital status	Education	Charlson Index b
EQ-5D[c]	-.17*	-.20**	.09	-.11	.08	-.31**
IIQ[d] Physical activity	.10	.03	-.16*	.09	-.20**	-.05
IIQ Social relations	.05	.14*	-.09	.15*	-.16*	.05
IIQ Travelling	-.01	-03	-.10	.06	-.12	-.06
IIQ Emotional health	.08	-.03	-.17*	.11	-.02	.02
IIQ Total score	.05	.02	-.15*	.12	-.11	-.06

* Correlation is significant at the .05 level (2- tailed). ** Correlation is significant at the 0.01 level (2-tailed).

[a] Social Economic Status; Dependening of income, employment and educational level according to the postal code of the area the participants live in (Netherlands Institute for Social Research, SCP 2006).

[b] Charlson index: weighted risk of mortality <1 year, dependent on co-morbidity.

[c] Euroqol 5D; range – 0.33 to 1 with lower number indicating a greater decrease in quality of life.

[d] IIncontinence Impact Questionnaire; range 0 to 100 with higher numbers indicating a greater decrease in quality of life.

Table 3 Results of ordinary least square regression analyses for general and condition-specific quality of life measurements

	EQ-5Dd (n=162) Score -.33- 1	IIQe total (n=155) Score 0 - 400	IIQ phys (n=155) Score 0 - 100	IIQ travel (n=155) Score 0 - 100	IIQ social (n=155) Score 0 - 100	IIQ emot (n=155) Score 0 - 100
Coefficients[a]						
SES	.16*	-.15	-.18*	-.10	-.09	-.17*
Marital Status	-.01	3.31	1.40	1.26	7.33	4.09
Age	.03	-.20*	-.10	-.17	-.12	-.16
BMI	-.05	-.05	-.01	.01	.09	-.09
Education	-.11	-.02	-.16	-.01	-.01	.02
Co-morbidity	-.26**	-.02	-.09	-.03	.01	.08
R^2	.12**	.06	.10**	.03	.06	.07
Type of urinary incontinence (UI)[b]						
Stress	.01	-4.15	-3.90	-4.62	-1.90	-7.81*
Urgency	-.06	2.38	-3.34	3.38	-1.61	.98
R^2 change	.02	0.04*	.02	.04	.01	.06**
Severity of UI[c]						
Moderate	.00	1.57	2.19	1.98	1.25	2.15
Severe	-.10**	17.17**	14.87**	13.89**	22.92**	21.72**
R^2 change	.06**	.15**	.09**	.07**	.12**	.14**

*p < 0.05. **p < 0.01.

[a] Standardized coefficients noted for SES, Age, BMI, Education, and Co-morbidity. Unstandardized coefficients noted for Marital status, Type UI, and Severity UI.

[b] Reference mixed UI

[c] Reference slight UI

[d] Euroqol 5D (Eq-5D); range from – 0.33 to 1 with lower numbers indicating a greater decrease in quality of life.

[e] Incontinence Impact Questionnaire; range 0 to 100 with higher numbers indicating a greater decrease in quality of life.

As shown in Table 3, after adjusting for the effect of confounders, patients with severe urinary incontinence score significantly lower on the EQ-5D and significantly higher on the IIQ-7 total score, and on all sub-domains, compared to patients with slight severity of urine loss. Furthermore, also after adjusting for the effect of confounders, patients with stress urinary incontinence score significantly lower on the emotional health domain compared to patients with mixed urinary incontinence, whilst there is no difference between urgency urinary incontinence and mixed urinary incontinence.

DISCUSSION

The present study assessed the impact of different levels of severity and types of urinary incontinence on the patient's generic and condition-specific quality of life.

Some characteristics of our study population were also significantly related to the quality of life and (the most relevant) are described in the Results section. In summary: a higher age, higher BMI and more co-morbidity negatively influence the generic quality of life. The negative relation between SES and the condition-specific quality of life indicates the opposite, because the higher the SES the better the quality of life.

However, the most important outcome is that about half of the participants were troubled by mixed urinary incontinence (50.7%) and a moderate severity of urine loss (48.9%); this mixed urinary incontinence had a greater impact on the emotional domain of the condition-specific quality of life as compared to stress urinary incontinence, although there is no difference compared with urgency urinary incontinence.

Women with symptoms of stress urinary incontinence are less dependent on their urine loss because they tend to lose urine during situations which are generally known to them and thus might be avoided[26]. However, the degree of severity of the incontinence influences both the generic and the condition-specific quality of life.

Compared to patients with slight urinary incontinence, patients with severe urinary incontinence (23%) experience more impact of urinary incontinence on all domains of the condition-specific quality of life, as well as on the condition-specific quality of life total score. Moreover, severe urinary incontinence also diminishes the generic quality of life compared to slight urinary incontinence, whilst there is no effect of moderate severity on quality of life as compared to slight severity of urine loss. Therefore, it appears that the severity of the symptoms, rather than the type of urinary incontinence, is a greater predictor for a decreased quality of life.

Comparison with existing literature

As mentioned above, mixed urinary incontinence is associated with lowered condition-specific quality of life as compared to stress urinary incontinence, as also reported by Schimf et al., whereas there is no significant difference with regard to urgency urinary incontinence, as also reported by Frick et al[15, 16].

When increased, symptom severity (as measured by the IIQ-7) diminishes the condition-specific quality of life in general, as also found by Tennstedt et al. and Huang et al[6, 27].

No differences were found between the types of urinary incontinence and their effect on the generic quality of life. This result is consistent with findings of Grimby et al. and Coyne et al. but in contrast to Botlero et al. who argue that mixed urinary incontinence is associated with a larger reduction in overall wellbeing[26, 28, 29]. However, in the latter study mixed urinary incontinence had more impact on emotional wellbeing and mood, which in our study is described as the emotional domain of the condition-specific quality of life. Differences in the choice of measurements and interpretation might be the reasons for the differences found between these studies.

Strengths and limitations

In this population-based study, women were included on the basis of randomizing their GP. However, because these women are a random selection (based on age ≥ 55 years), at the time of screening it is unknown whether they have already asked for help, either recently or in the past.

In the primary care setting these women with urinary incontinence have rarely been studied.

In the present study, different types of urinary incontinence as well as the severity of its symptoms and effects on quality of life were explored, whereas other studies mainly investigated either the type or the severity of urinary incontinence.

Also, this study uses both generic and condition-specific questionnaires, which is recommended by Dugan et al. and Naughton et al.; the latter in particular report that the IIQ and EQ-5D are highly recommended[13, 21]. The use of both questionnaires allows to assess symptom distress as well as general wellbeing.

Self-administered questionnaires (allowing a person to judge their own health status) are important for the present study. However, self-reports on the type of urinary incontinence and severity of symptoms can lead to a potential bias in data because of subjective symptom perception[3].

Another potential limitation of this study is the inclusion of women who participated because they already have symptoms, thus precluding comparison with women without urinary incontinence. Also, women suffering from urinary incontinence may already experience a somewhat diminished quality of life.

The willingness to participate was 48%, which was more than expected at the start of the trial. However, any loss is a limitation and in this study the main reasons for non-response were: too great a burden to participate (19.7%), not wishing to undergo more examinations/research in this or other areas (17.4%), and being too old (15.5%, with a mean age of 72 years).

Also, because this study has a cross-sectional design with only one measuring point, the direction of the causal relationship between urinary incontinence and (factors of) quality of life cannot be determined, as this association could also be bidirectional.

Finally, because this study included only women in the Netherlands aged ≥ 55 years, these results cannot be extrapolated to other cultures and are not generalizable to all ages.

Implications for future research

The use of different types of measurements can provide valuable information for future research. However, we need to establish which measuring instrument is most effective to study the relation between urinary incontinence and quality of life, or whether the use of two or more questionnaires may be a better approach to obtain maximum insight on this topic[11, 13].

We recommend to perform a longitudinal study, with several measuring points, to assess whether changes in symptoms are related to changes in quality of life. Performing a population-based study will allow comparisons to be made between patients with and without urinary incontinence, and to establish differences in generic quality of life due to the impact of urinary incontinence.

More research is required on differences between the types urinary incontinence and their effect on quality of life, especially with regard to urgency urinary incontinence.

In addition, the level of burdensomeness may differ between age groups because some symptoms and complaints are often assumed (like co-morbidity) to 'belong' to older age. Studying younger women with urinary incontinence (albeit a smaller group) may increase our knowledge on the impact of urinary incontinence on the quality of life.

Finally, due to the aging of society and knowing that urinary incontinence increases with age, early detection and treatment is an important part of future care and other considerations related to rising costs.

CONCLUSIONS

This study shows that the severity of symptoms, not the type of urinary incontinence, is a greater predictor for a decreased (generic and condition-specific) quality of life. Knowledge on the impact of the level of severity, in relation to the burden for incontinent women, may increase GPs' insight into the consequences of the symptoms of urinary incontinence, with the aim to improve care and increase the patient's quality of life.

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CHAPTER 7

The impact of urinary incontinence on sexual functioning in community-dwelling older women

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Journal of Sexual Medicine, 2014; 11: 1757-1765

ABSTRACT

Introduction

Knowledge on the sexual health of patients with urinary incontinence in primary care is scarce; therefore, the impact of urinary incontinence on sexual functioning was examined in community-dwelling older women.

Aim

To provide primary healthcare professionals with more information on the sexual health of older women with urinary incontinence, which can be used to discuss this sensitive topic during a consultation.

Methods

A cross-sectional survey among the 350 women aged ≥55 years participating in a primary care trial on urinary incontinence.

Main outcome measures

Among patients with a partner, sexual problems of the sexually active patients were described as well as reasons for not being sexually active. A multivariate logistic regression model was performed to identify factors that are predictors of sexual activity, and odds ratios (ORs) and 95% confidence intervals (CIs) were estimated.

Results

Of all participants with a partner, 68% (95%-CI: 61-74) were sexually active. Of these, 25% (95%-CI: 17-35) felt restricted in (or avoided) sexual activity due to their urinary incontinence. Urine leakage during sexual activity was present in 26% (95%-CI: 19-34). The most frequent reason for not being sexually active was a physical problem of their partner (28%, 95%-CI: 18-40); only 5% (95%-CI: 2-13) reported that urinary incontinence was a reason for not having sex. Increasing age was the only independent (negative) predictor of sexual activity (OR 0.95, 95%-CI: 0.90-1.00).

Conclusions

Most of these older women with urinary incontinence were sexually active, if they had a partner. The main reason for not being sexually active was a partner-related problem. Although for only 5% was urinary incontinence the main reason for not having sex, about 25% of the sexually active women reported a negative influence of urine loss on their sex life. This implies that assessing sexual function is relevant in older women with urinary incontinence.

INTRODUCTION

A healthcare professional should be aware of the potential existence of sexual problems in women with urinary incontinence and an active attitude towards this problem is recommended. Secondary care studies have shown that urinary incontinence and other pelvic floor disorders in women is associated with sexual dysfunction[1-4]. Since sexual wellbeing is an important element of health, dysfunction may lead to a decrease in quality of life[5].

Successful conservative and surgical treatments of urinary incontinence are associated with improvement in sexual function[6]. However, besides urinary incontinence, sexual dysfunction is also a topic that patients may not easily discuss with a professional, even though Dutch guidelines advise general practitioners (GPs) to ask patients with urinary incontinence about the impact of her symptoms on sexuality[7-9]. Knowledge on the sexual health of patients with urinary incontinence in primary care is still scarce. In particular, predictors for sexual activity in older women with urinary incontinence have not yet been established in a population-based study[10-12].

AIMS

This study examines how the sexual activity of community-living older women is affected by urinary incontinence and identifies associated sexual problems. The aim is to provide primary healthcare professionals with more knowledge on the sexual health of older women with urinary incontinence, which may be used to initiate and discuss this sensitive topic during a consultation.

METHODS

Patients and design

This is a cross-sectional survey of the 350 participants of the URinary INcontinence in Older women (URINO) trial (Dutch Trial Register number NTR1181)[8, 13, 14]. In short, the URINO trial is a randomized controlled trial in primary care on the effects and cost-effectiveness of actively encouraging older women with urinary incontinence to undergo diagnosis and treatment. Participants are females aged ≥55 years from primary care, suffering from urinary incontinence, who gave their written informed consent.

Approval for the study was obtained from the Medical Ethical Review board of the University Medical Centre Groningen (UMCG), the Netherlands.

Data and main outcome measures

In the URINO trial, patients were interviewed at baseline and filled in self-administered questionnaires. The type of incontinence was identified by means of question 4 of the International Consultation on Incontinence Questionnaire (ICIQ-UI-SF): `*When does urine leak? Please tick all that applies to you*`[15]. The amount and frequency of urine loss were assessed using the Incontinence Severity Index (ISI)[16]. The impact of urinary incontinence on daily life was measured on a scale from 0-10 as filled in

Questionnaire about sexual activity
(Questions 1-5, 8 and 9 are derived from the Sexual Activity Questionnaire, and questions 6 and 7 from the Pelvic organ prolapse/urinary Incontinence Sexual Questionnaire)

1. Are you currently married or having an intimate relationship with someone?
   - o Yes
   - o No (questionnaire finished)
2. How often did you engage in sexual activity last month? Think not only of sexual intercourse, but also of other ways of lovemaking that are exciting for you or your partner
   - o 5 times or more (go on to question 4)
   - o 3-4 times (go on to question 4)
   - o 1-2 times (go on to question 4)
   - o Never (go on to question 3)
3. I am not sexually active at the moment because: (please tick as many of these items as apply)
   - o I am too tired
   - o My partner is too tired
   - o I am not interested in sex
   - o My partner is not interested in sex
   - o My partner has physical problem which makes sexual activities difficult or uncomfortable
   - o I have symptoms of pelvic organ prolapse which make sexual activities difficult of uncomfortable
   - o Sexual intercourse is painful
   - o I have symptoms of urinary incontinence which make sexual activities uncomfortable
   - o I have another physical problem which makes sexual activities difficult or uncomfortable
   - o Other reason (please describe) _____
4. How did the frequency of sexual activity last month compare with what is usual for you?
   - o Much more
   - o Somewhat more
   - o A little
   - o Not at all
5. Were you satisfied with the frequency of sexual activity last month?
   - o Very much
   - o Somewhat
   - o A little
   - o Not at all
6. Are you incontinent of urine (leak urine) with sexual activity?
   - o Always
   - o Usually
   - o Sometimes
   - o Seldom
   - o Never
7. Does urinary incontinence restrict your sexual activity?
   - o Always
   - o Usually
   - o Sometimes
   - o Seldom
   - o Never
8. Do you avoid sexual activity because of urinary incontinence?
   - o Always
   - o Usually
   - o Sometimes
   - o Seldom
   - o Never
9. Do you feel pain during sexual intercourse?
   - o Very much
   - o Somewhat
   - o A little
   - o Not at all

Box 1 Questionnaire about sexual activity and related problems

on question 3 of the ICIQ-UI-SF: `*Overall, how much does leaking urine interfere with your everyday life? Please ring a number between 0 (not at all) and 10 (a great deal)*'[15]. The burden of urinary incontinence was defined as the sum score of the Urinary Distress Inventory (UDI)[17, 18]. The incontinence specific quality of life was measured by the Incontinence Impact Questionnaire (IIQ-7)[17, 18]. The Geriatric Depression Score (GDS) and Groningen Activity Restriction Scale (GARS) were used to assess depressive symptoms and functional status, respectively[19, 20]. In case patients were married or involved in another committed relationship, they were asked to answer 7 questions from the Sexual Activity Questionnaire (SAQ) and two questions from the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ) (Box 1)[21, 22]. These questions were selected based on their relevance for our research question. Due to the delayed addition of the questionnaire on sexuality to the study protocol, it was not offered to the first 56 participants of the URINO trial.

Statistical analysis

Characteristics of the study population, marital status, reasons for not being sexually active and the sexual problems of the sexually active patients, were described. Based on the answer to the question about frequency of sexual activities, patients were divided into two groups: sexually active women and sexually inactive women. To identify factors related to sexual activity of older women with urinary incontinence, the characteristics of these two groups were compared. Univariate logistic regression analyses were performed and odds ratios (ORs) and 95% confidence intervals (CIs) were calculated. Factors significantly associated with sexual activity in the univariate analysis were fitted into a multivariate logistic regression model using a backward procedure, to develop a prediction model for being sexually active. Because current coital incontinence can only be assessed in women who are still sexually active, this potential determinant of sexual inactivity could not be included in the prediction model for being sexually active. Data were analyzed using SPSS 20.0 for Windows. A p-value of <0.05 was considered to be statistically significant.

RESULTS

Patient characteristics

Table 1 presents the characteristics of the total study population (n=350). Most patients were suffering from mixed urinary incontinence of a moderate severity. Of the 294 women who filled in the sexuality questionnaire, 196 (67%, 95%-CI: 61-72) indicated that they were married or in another committed relationship, and 96 (33%, 95%-CI: 28-38) had no partner (Figure 1). Of the 196 patients with a partner, 188

patients answered the question on being sexually active (of the remaining 8 patients, 6 skipped that question but filled in the rest of the questionnaire and were thus considered to have a partner). Of these 188 women, 127 (68%, 95%-CI: 61-74) were sexually active and 61 (32%, 95%-CI: 26-39) were not. Of the total study population, 2 patients (<1%) refused to fill in the questionnaire about sexual activity.

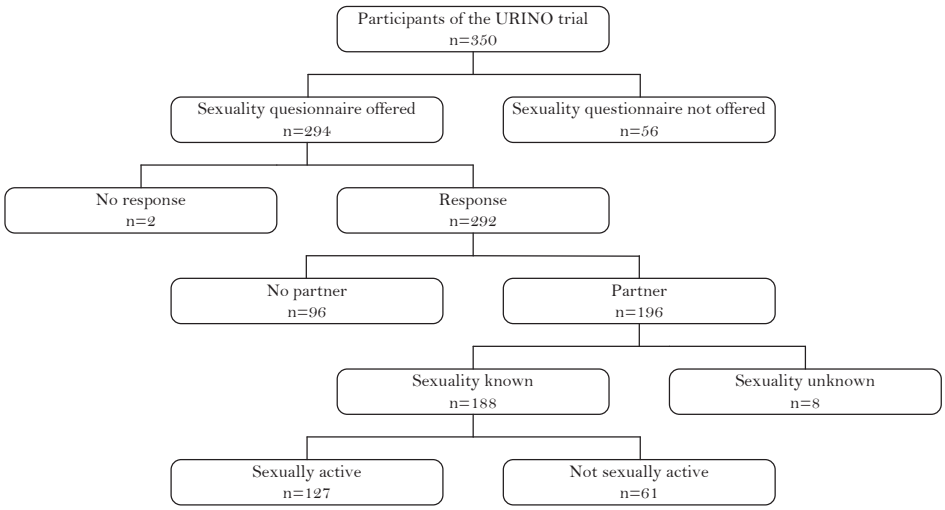

Figure 1 Flowchart of the study population

Reasons for not being sexually active

The most common reasons for not being sexually active were a physical problem of their partner (n=17, 28%, 95%-CI: 18-40), pain during intercourse (n=15, 25%, 95%-CI: 16-37), and a lack of interest for sexual activities (n=12, 20%, 95%-CI: 12-31) (Table 2). Of the 61 sexually inactive patients, 3 (5%, 95%-CI: 2-13) mentioned urinary incontinence as a reason for not having sex.

Sexual problems in patients who are sexually active

Table 3 lists the problems of the sexually active patients (n=127). Urine leakage during sexual activity (ranging from seldom to always) was present in 32 (26%, 95%-CI: 19-34) of the patients who answered that question; 22 (n=24%, 95%-CI: 16-33) felt limited in their sexual activity by urinary incontinence; and 14 patients (15%, 95%-CI: 9-24) avoided sexual activity because of urinary incontinence. In total, 25% (95%-CI: 17-35) either felt restricted in their sexual activity due to urinary incontinence or avoided sexual activity.

Table 1 Characteristics of the total study population of women with urinary incontinence (n=350) and of patients with a partner of whom sexual activity is known (n=188)

	Total study population	With a partner and sexual activity known
Age in years; mean (SD)	65.57 (8.32)	63.70 (6.92)
Body mass index; mean (SD)	27.32 (5.08)	27.23 (4.62)
Education level		
Low; n (%)	81 (23.1)	29 (15.4)
Medium; n (%)	153 (43.7)	90 (47.9)
High; n (%)	116 (33.1)	69 (36.7)
Relationship status		
Married/committed relationship; n (%)	196 (56.0)	188 (100.0)
Single; n (%)	96 (27.4)	-
Unknown; n (%)	58 (16.6)	-
Sexually active (among patients in a relationship); n (%)	127 (64.8)	127 (64.8)
Childbirth ≥ 1; n (%)	310 (88.6)	170 (90.4)
Type of urinary incontinence		
Stress; n (%)	96 (27.4)	55 (29.3)
Urge; n (%)	65 (18.6)	31 (16.5)
Mixed; n (%)	177 (50.6)	95 (50.5)
Unknown; n (%)	12 (3.4)	7 (3.7)
Severity of urinary incontinence		
Slight; n (%)	88 (25.1)	61 (32.4)
Moderate; n (%)	169 (48.3)	86 (45.7)
(Very) severe; n (%)	84 (24.0)	38 (20.2)
Unknown; n (%)	9 (2.6)	3 (1.6)

Table 2 Reasons for not being sexually active among patients with a partner (n=61)

	n (%)
My partner has got a physical problem which makes sexual activity difficult or unpleasant	17 (27.9)
Sexual intercourse is painful	15 (24.6)
Other	14 (23.0)
I'm not interested in sex	12 (19.7)
I'm too tired	9 (14.8)
I've got another physical problem which makes sexual activity difficult or unpleasant	8 (13.1)
I'm suffering from genital prolapse which makes sexual activity difficult or unpleasant	5 (8.2)
My partner is not interested in sex	5 (8.2)
My partner is too tired	4 (6.6)
I'm suffering from urinary incontinence which makes sexual activity difficult or unpleasant	3 (4.9)

Table 3 Sexual-related problems of sexually active women with urinary incontinence (n=127)

	n (%)
Incontinent of urine with sexual activity	
Always	0 (0.0)
Usually	1 (0.8)
Sometimes	14 (11.0)
Seldom	17 (13.4)
Never	93 (73.2)
Unknown	2 (1.6)
Restricted in sexual activity by urinary incontinence	
Always	0 (0.0)
Usually	0 (0.0)
Sometimes	13 (10.2)
Seldom	9 (7.1)
Never	69 (54.3)
Unknown	36 (28.3)
Avoiding sexual activity because of urinary incontinence	
Always	0 (0.0)
Usually	0 (0.0)
Sometimes	4 (3.1)
Seldom	10 (7.9)
Never	77 (60.6)
Unknown	36 (28.3)
Pain during sexual intercourse	
Very much	4 (3.1)
Somewhat	7 (5.5)
A little	33 (26.0)
Not at all	75 (59.1)
Unknown	8 (6.3)

Factors associated with being sexual active in patients with a partner

When comparing the sexually active and sexually inactive patients with a partner, significant differences were shown in the univariate analyses regarding age, amount of urine loss, impact of urinary incontinence on daily life, overactive bladder symptoms, depression and mobility (Table 4). In the multivariate logistic regression model, in which all these factors were initially included, increasing age was the only independent (negative) predictor of being sexually active (OR 0.95, 95%-CI: 0.90-1.00).

Table 4 Characteristics of sexually active and sexually inactive women with urinary incontinence and predictors for being sexually active.

	Sexually active	Sexually inactive	Univariate logistic regression		Multivariate logistic regression	
	n=127	n=61	OR (95%-CI)	p	OR (95%-CI)	p
Age in years; mean (SD)	62.7 (6.7)	65.7 (7.0)	0.94 (0.90-0.98)	0.01	0.95 (0.90-1.00)	0.04
Number of comorbid factors*; median (IQR)	2 (1-3)	2 (1-3)	0.92 (0.76-1.11)	0.39		
Self-reported type of incontinence						
Stress incontinence; n (%)	42 (33.1)	13 (21.3)	1			
Urgency incontinence; n (%)	19 (15.0)	12 (19.7)	0.49 (0.19-1.27)	0.14		
Mixed incontinence; n (%)	61 (48.0)	34 (55.7)	0.56 (0.26-1.18)	0.12		
Unknown; n (%)	5 (3.9)	2 (3.3)	0.77 (0.13-4.47)	0.77		
Frequency of urinary incontinence						
Less than once a month (%)	19 (15.1)	10 (16.4)	1			
A few times a month; n (%)	42 (33.3)	13 (21.3)	1.70 (0.63-4.56)	0.29		
A few times a week; n (%)	28 (22.2)	15 (24.6)	0.98 (0.37-2.64)	0.97		
Every day and/or night; n (%)	37 (29.4)	23 (37.7)	0.85 (0.34-2.14)	0.73		
Amount of urine loss						
Drops; n (%)	70 (55.6)	22 (36.7)	1			
Small splashes; n (%)	51 (40.5)	35 (58.3)	0.46 (0.24-0.87)	0.02		
More; n (%)	5 (4.0)	3 (5.0)	0.52 (0.12-2.37)	0.40		
Impact on daily life score; median (IQR)	2 (0-4)	3 (1-5)	0.85 (0.73-0.96)	0.010	‡	
UDI overactive bladder score†; median (IQR)	38.9 (11.1-66.7)	44.4 (30.6-66.7)	0.99 (0.98-0.99)	0.031	‡	
UDI urinary incontinence score†; median (IQR)	26.7 (13.3-40.0)	26.7 (13.3-53.3)	0.99 (0.98-1.00)	0.192		
UDI nocturnal incontinence score†; median (IQR)	0.0 (0.0-0.0)	0.0 (0.0-0.0)	1.00 (0.97-1.04)	0.888		
UDI obstructive micturition†; median (IQR)	0.0 (0.0-33.3)	0.0 (0.0-33.3)	1.01 (0.99-1.02)	0.310		
UDI pain and discomfort score†; median (IQR)	5.6 (0.0-22.2)	11.1 (0.0-31.9)	0.99 (0.98-1.01)	0.343		
UDI genital prolapse score†; median (IQR)	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.99 (0.98-1.01)	0.558		
IIQ total score†; median (IQR)	4.8 (0.0-14.3)	9.5 (0.0-17.9)	0.98 (0.96-1.00)	0.113		
GDS score†; median (IQR)	0 (0-1)	1 (0-2)	0.81 (0.66-0.99)	0.040	‡	
GARS total score†; median (IQR)	19 (18-22)	18 (18-19)	0.91 (0.84-0.99)	0.023	‡	

*number of diseases of the following list: diabetes, cerebral vascular incidents, myocardial infarction, angina pectoris, congestive heart failure, hypertension, atherosclerosis, COPD, dizziness with falling, severe or persistent back pain, joint problems, constipation, visual impairment, malignancies, abdominal surgery; † UDI: Urogenital Distress Inventory, IIQ: Incontinence Impact Questionnaire, GDS: Geriatric Depression Scale, GARS: Groningen Activity Restriction Score; ‡ removed from multivariate model

DISCUSSION

Main findings

In this cross-sectional survey among older women with urinary incontinence, 68% were sexually active and 25% of them felt restricted in their sexual activity due to her symptoms, or avoided it. Only 5% of the sexually inactive patients reported urinary incontinence as a reason for not having sex; one of the main reasons for not having sex was related to their partner. Increasing age proved to be the only (negative) predictor of being sexually active (OR 0.95, 95%-CI: 0.90-1.00); type and severity of incontinence symptoms played no role in this.

Comparison with existing literature

In our study the percentage of sexually active patients is similar to that in a primary care population among older community-dwelling women (with either urinary incontinence or pelvic organ prolapse) as reported by Barber et al., i.e. 68% (95%-CI: 61-74) and 70% (95%-CI: 63-75), respectively[12]. Nilsson et al. found a higher prevalence rate of 86% (95%-CI: 81-91) in their community-dwelling women, but their study group was aged ≥18 years[10]. Our finding that the prevalence of sexual activity declines with age, as also reported by others, may be explained by a decrease in libido and an increase in physical limitations as women become older[23, 24].

In our group, a physical problem of the partner was the most common reason for not being sexually active (28%, 95%-CI: 18-40). In the study of Barber et al. this was also the most frequently mentioned reason, although reported by a higher percentage of women (63%, 95%-CI: 51-73)[12]. An explanation for this difference may lie in the mean age of the sexually inactive patient and her partner, i.e. the older the patient, the more likely that her partner has physical problems that prevent sexual activity. In that case, the mean age of the sexually inactive patients in the study of Barber et al. should be higher than the 66 years of our sexually inactive patients; however, information on age was not reported by those authors[12]. Only 5% of our patients (95%-CI: 2-13) mentioned urinary incontinence as a reason for not having sex, considerably less than the 20% (95%-CI: 12-31) reported by Barber et al; however, those authors combined urinary incontinence and pelvic organ prolapse as reasons for not being sexually active, whereas we only asked about urinary incontinence.

In our study population, a prevalence of 26% (95%-CI: 19-34) urinary incontinence was found during sexual activity, which is significantly lower than the 60% (95%-CI: 54-65) reported by Jha et al. in a clinical population[4]. This difference might be attributable to differences in study populations. The patients of Jha et al. consisted mainly of women with stress urinary incontinence, whereas our patients mainly suffered from mixed urinary incontinence. On the other hand, because Jha et al. did not

report on severity of symptoms, it is unclear whether the difference in prevalence of urinary incontinence during sexual intercourse between their study and ours can be attributed to this. In addition, it is unclear whether different types/levels of severity of urinary incontinence influence the degree of impact of urinary incontinence on sexual functioning; the literature on this topic is conflicting[6]. Moreover, Oh et al. (in a secondary care population in which the two main types of urinary incontinence were equally distributed) and Nilsson et al. (in a primary care population of women with urinary incontinence, mainly stress urinary incontinence and pelvic organ prolapse) reported comparable prevalence rates of urinary incontinence during sexual activity, i.e. 38%, 95%-CI: 31-46 and 34%, 95%-CI: 26-41, respectively[3, 10].

In our study, 25% (95%-CI: 17-35) of the patients either felt restricted in their sexual activity due to urinary incontinence or avoided sexual activity. In the study of Temml et al. (including participants of a free health survey aged ≥20 years), 25% (95%-CI: 21-30) of the women with urinary incontinence reported some negative impact of urinary incontinence on sexual function[5]. Although these percentages are comparable to ours, their population was younger (≥20 vs. ≥55 years) and differed regarding the definition of the outcome measurement (i.e. Temml et al. asked 'To what extent do you feel that your sex life has been spoiled by urinary leakage?')[5].

Strengths and limitations

Sexual function in older community-dwelling women with urinary incontinence has not been frequently studied. In our population ≥ 99% of the participants agreed to fill in the questionnaire about sexual activity, thereby providing robust data. An important strength of our study is that, preceding the questions about sexual activity, we asked patients whether they were married or in another committed relationship. We have chosen this from the logical reasoning that having a partner or not is the most important predictor for being sexually active or not; in order to prevent biased results, only patients with a partner were eligible to answer questions about sexual activity. But ideally, to get even more insight to the impact of urinary incontinence on sexual functioning, we also should have asked whether not having a partner is related to the symptoms of urinary incontinence. Also, promiscuity was not an option to choose for and this might have given an underestimation of the number of sexual active women, although the prevalence of promiscuity was probably low in the older female population under study.

To our knowledge, this is the first study to fit a prediction model for sexual activity in older women with urinary incontinence. We found that, although urinary incontinence has a negative influence on sexual activity, age is a better predictor. Duration of symptoms of urinary incontinence is not measured with standard questionnaires. As it might be a predictor of sexual activity, and because little is known about the

influence if this variable, we recommend that it should be addressed in future research in this field.

We used questions from the PISQ and the SAQ that were the most relevant for the present study. An advantage of this is that our questionnaire was relatively short, thereby probably increasing the response rate. A disadvantage of this choice is that we did not use validated questionnaires about sexual functioning, which implies that comparison of our results with other studies may be difficult[1]. It should be noticed that in case of a sensitive subject as sexual activity, always some unreliability has to been taken account by the acquired data; it is imaginable that socially desirable answers are given. But by asking the questions about sexuality by means of a questionnaire and not by means of an interview, we aimed to reduce this risk at unreliable answers as much as possible.

CONCLUSIONS

In this group of older women with urinary incontinence, the majority were sexually active if they had a partner. The most frequently mentioned reason for not being sexually active was a partner-related problem. Although urinary incontinence was seldom the main reason for not having sex, GPs should be aware that about 1 in 4 of sexually active patients feels restricted in her sexual activity (or avoids it) due to symptoms of urinary incontinence. This implies that assessing sexual function is relevant in older women with urinary incontinence. To gain insight into the impact of urinary incontinence on sexuality, GPs can ask whether a patient has an intimate relationship and whether she is sexually active. If she is not, the reason for this and the influence of urinary incontinence on her sexual inactivity can be explored. If a woman is sexually active, the GP may explore whether she experiences any problems in her sexual functioning. All information obtained can be taken into account when establishing a treatment plan for older community-living women with urinary incontinence.

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CHAPTER 8

Summary, general discussion and future perspectives

The main objective of this thesis was to study the effects and cost-effectiveness of offering diagnostic testing and tailored treatment to older community-dwelling women with urinary incontinence as compared with standard care, in a population that did not seek help on their own initiative. Community-dwelling older women who were positively screened for urinary incontinence, were invited to undergo a diagnostic assessment and subsequent treatment (i.e. the intervention group), or to receive care as usual; this implies that, for this latter group, diagnostic testing and treatment only took place when they decided to consult their general practitioner (GP) for urinary incontinence (i.e. the control group).

This chapter summarises and discusses the main results, presents suggestions for further research, and considers the implications for healthcare practice.

SUMMARY OF MAIN RESULTS

Chapter 2 describes the effect of treatment uptake after screening community-dwelling older women for urinary incontinence. All patients in the intervention group of the URINO trial underwent diagnostics; treatment uptake in that group was 80% compared with only 2% in the control group. The conclusion drawn is that, to increase treatment uptake, screening for urinary incontinence must be followed by active encouragement to undergo diagnostic evaluation and treatment. After applying the Wilson and Jungner criteria, it was evaluated whether female urinary incontinence in older women is a condition suitable for screening[1]. Although most of these criteria are met, it remains unclear whether treating a patient who is at risk of developing urinary incontinence, but is still symptomless, actually prevents urinary incontinence. In addition, the natural history of urinary incontinence is not completely understood. Finally, the importance of screening for the patients themselves is also not totally clear; however, the high response and participation rates of the URINO trial suggest that at least a substantial part of the non-help-seeking population is willing to accept an invitation for diagnostic testing and treatment. The URINO trial was designed to study whether offering diagnostic testing and treatment to a population that did not seek help on their own initiative did have a beneficial effect on symptoms.

Chapter 3 investigates the effects of actively encouraging older community-dwelling women with urinary incontinence to be diagnosed and treated. At the 12-months follow-up, symptom severity, number of daily incontinent episodes and quality of life were compared between the two URINO trial study groups. Participants in both groups mainly suffered from mixed urinary incontinence of moderate severity; this implies that the URINO population is a realistic sample of the open population[2]. The percentage of patients that improved in terms of severity of symptoms was 34% in the

intervention group and 17% in the control group. The probability that the severity of symptoms of patients in the intervention group would improve was nearly two times higher compared with the control group (OR 1.9, 95% CI 1.1 to 3.3). The probability of a reduction in the number of incontinence episodes also increased (OR 2.5, 95% CI 1.5 to 4.1): in the intervention group the median number of incontinence episodes per day decreased from 1.0 to 0.0, whereas in the control group this remained at 1.0 episode per day. Although both trial groups reported a better quality of life after 12 months, no difference regarding a change in quality of life between the two groups could be detected. The conclusion is that actively encouraging older community-dwelling women to undergo diagnosis and treatment results in less severe symptoms and fewer episodes of urinary incontinence as compared with standard care, but does not necessarily result in a difference in improvement in quality of life.

Chapter 4 reports on the analysis of the cost-effectiveness of the intervention in the URINO trial. In this analysis, the primary measure of effect was the impact on daily life of the incontinence symptoms. Costs per extra life-year without impact from urinary incontinence amounted to €5,179. Assuming a ceiling ratio (the maximum amount that a decision-maker is willing to pay for health effect) of €20,000, the probability that the intervention is cost-effective based on impact on daily life was 91%. Thus, the positive clinical effects of the intervention can be achieved against acceptable costs, with an improvement of symptom-specific quality-adjusted life-years (IIALYs).

Chapter 5 describes which women aged 55 years and older might benefit from a systematic screening on urinary incontinence. Two thirds of the URINO participants were not registered with this diagnosis by their GP and these women are on average younger (OR 0.91, 95% CI 0.87 to 0.96) and have lower levels of distress due to their urogynaecological symptoms (OR 0.95, 95% CI 0.92 to 0.98) than women with a registered diagnosis. Severity of symptoms of urinary incontinence was not a predictor for seeking help. However, remarkably, the most common reason for not consulting a GP was that the patient considered that their symptoms were not severe enough for a consultation (73%).

In *chapter 6* it is shown that severity, not type, of urinary incontinence was the main predictor of a decreased quality of life in elderly women with urinary incontinence: patients with severe symptoms experienced more impact of urinary incontinence on all domains of condition-specific and general quality of life compared with patients with slight urinary incontinence, in whom the type of incontinence had only a limited effect on quality of life.

Chapter 7 explores the impact of urinary incontinence on sexual activity among participants with a partner. Most of these women (68%) were sexually active and the most frequently mentioned reason for not being sexually active was a partner-related problem (28%). In a minority of women the main reason for not having sex was

urinary incontinence (5%); however, about 25% of the sexually active women reported a negative influence of the urine loss on their sex life. This implies that assessing sexual function is relevant in older women with urinary incontinence.

COMPARISON WITH EXISTING LITERATURE

A screened population

Participants of the URINO trial were screened by means of a postal questionnaire on their symptoms of urinary incontinence and, if they screened positive, they were invited to undergo diagnostic testing and treatment. Screening a population at risk will improve case-finding. In this thesis it is described that one of the ten criteria of Wilson and Jungner for responsible and acceptable screening that was not yet met was: 'Are the costs of case-finding economically balanced in relation to possible expenditure on medical care as a whole?'[1, 3]. In the URINO trial it was found that treating a population with urinary incontinence that did not seek help on their own initiative has a positive effect on symptoms against acceptable costs. This suggests that screening of older community-dwelling women on urinary incontinence might be meaningful.

Screening an older population for common disorders, even when only some of the patients with that condition seek help on their own initiative, is not new. For example, Eekhof et al. investigated the effect of screening for disorders in an older population[4]. These authors screened subjects aged 75 years and older on four common disorders (hearing and visual disorders, urinary incontinence, and mobility disorders). When screened positively and if this was new to the GP, and if the GP and patient considered it necessary, patients were invited for a consultation. Subsequently, they received an intervention (implying usual care). In that study, the prevalence of urinary incontinence among the screened population was the same as that of urinary incontinence in the URINO trial (31%); however, the percentage of patients in whom the diagnosis urinary incontinence was new to the GP was not as high as that in the URINO trial (26% and 64%, respectively)[5]. An explanation for this might be that, in the URINO trial, in addition to consultations on this topic, the prescription of incontinence pads was also seen as 'known by the GP as suffering from urinary incontinence'. It is unclear, however, whether Eekhof et al. also included this item in their definition, or whether they only counted explicit consultations for urinary incontinence. In the study of Eekhof et al., 71% of their patients agreed to a consultation, whereas 100% of the participants in the intervention group of the URINO trial accepted the invitation for diagnostic testing. A possible explanation for this is that the invitation in the URINO trial may have been more encouraging. However, it is noteworthy that, in the

study of Eekhof et al., only 28% of the patients that discussed urinary incontinence with their GP eventually agreed to an intervention; in the URINO trial, treatment uptake was 80%. It is unclear in which way patients in the study of Eekhof et al. were informed about the available treatment options and to what extent their GP was convinced of the potential effect of these options. Nihilistic thoughts of both the physician and patient about the effect of treatment of urinary incontinence in the elderly may have played a role[6]. Finally, the intervention of Eekhof et al. did not result in a decrease in the prevalence of urinary incontinence; from this, the authors concluded that implementing a standardized screening programme is not recommended. However, whether the intervention was effective in terms of a reduction of the severity of symptoms was not measured. Thus, until now, there are no data that confirm the benefits of screening as a method to reduce the burden of suffering from urinary incontinence[7]. From the URINO trial it is now known that screening alone has an insufficient effect on treatment uptake: screening for urinary incontinence must be followed by active encouragement of the patients to participate in further diagnostics and treatment.

Effect of treatment

Of all patients in the intervention group of the URINO trial who started with any form of treatment (80%), the majority (85%) received pelvic floor muscle training. Thus, the positive effect of the URINO trial can be largely attributed to this type of conservative treatment for urinary incontinence. It is known that pelvic floor muscle training is effective in women with urinary incontinence who consult a physician and, from the results of the URINO trial, it is now known that this is also effective in a population that does not seek help on their own initiative[8-10].

The effect found in the URINO trial (OR 1.9, for improvement of severity of incontinence) is less than that revealed in a systematic review published by Imamura et al., on non-surgical treatments for women with urinary stress incontinence (OR 4.5)[11]. The results of the URINO trial are expected to be lower than that of Imamura et al., since their review only examined stress incontinence and because women of all ages were included in the reviewed trials. The effect of conservative treatment for urinary incontinence is generally larger in relatively young patients with genuine stress urinary incontinence as compared to older women with all types of incontinence[10, 12].

The percentage of patients that profited from the intervention in the URINO trial was significant but lower than expected. Based on the findings of Seim et al. in an observational study on the effect of treatment of urinary incontinence in women in general practice, an improvement was expected in 65% of the included patients in the intervention group and in 40% of the control group (the study showed improvement for 34% and 17% of the patients, respectively)[13]. In addition, treatment uptake in the

URINO trial was only 80% compared with 100% of the patients in the study of Seim et al. However, the study population of Seim et al. was not the same as that in the URINO trial: their patients were younger, more women were premenopausal, and the main type of urinary incontinence of their patients was stress incontinence, whereas the URINO population was mainly diagnosed with mixed symptoms. Finally, the population of Seim et al. suffered from severer symptoms at baseline than the URINO patients, which gave more room for improvement.

Costs

In the intervention group of the URINO trial, most costs were related to consultations with a pelvic physiotherapist. Mean overall costs in the intervention group were €417 and, after 12 months, this group gained on average 0.86 QALYs. For comparison, involving nurse specialists in primary care for urinary incontinence resulted after one year in a gain of 0.79 QALYs, against €677 of societal costs[14]. In addition, surgical treatment for urinary incontinence, involving suburethral sling placement and prolapse meshes, amounted to €1220 of average costs per patient, where 0.05 QALYs were gained at one-year post-operation[15]. Therefore, the costs of the intervention in the URINO trial were lower than these other treatment options and resulted in more health gain on the short term. This supports the statement that the costs of proactively approach older women with urinary incontinence and offering them diagnostic testing and treatment, are acceptable.

Continence promotion

From the high response and participation rates in the URINO trial (76% and 47%, respectively), it can be concluded that many patients appreciated the continence-promoting approach towards older community-dwelling women with urinary incontinence of the URINO trial. Whereas urinary incontinence used to be a condition with a 'taboo', much has been achieved in promoting awareness of urinary incontinence[7]. Efforts have been made to inform healthcare providers and patients of the fact that urinary incontinence is treatable; nevertheless, help-seeking behaviour and the related use of effective treatment options, is still limited. Awareness about continence is still not optimal and different strategies are being developed to improve care for incontinent older women who hesitate to seek care.

Holroyd-Leduc et al. studied the effect of a self-management tool for older community-dwelling women with urinary incontinence; the tool included 6 modifiable risk factors and associated strategies for behaviour change. In a prospective cohort study using an interrupted time-series design, they found a reduction of urinary leakage rates: a decrease in the number of daily incontinence episodes of 1.4 was reported[16]. The effect on the number of incontinence episodes was larger than in the URINO

trial; however, patients in the cohort of Holroyd-Leduc et al. had a higher number of daily incontinence episodes than in the URINO population (2.8 vs. 1.0, respectively) and their patients were mainly suffering from the most treatable type of urinary incontinence, i.e. stress incontinence, whereas the URINO patients mostly reported mixed symptoms[8]. Finally, in the study of Holroyd-Leduc et al. severity of symptoms was not an outcome measure.

In primary care, nurse-led continence services in which incontinence care is delivered using predetermined care pathways (as part of a randomized controlled trial among men/women aged ≥40 years by Williams et al.) were found to be effective: 59% of the patients in the intervention group improved in terms of symptoms as opposed to 48% of the control group[17]. The interventions included advice on diet and fluids, bladder training, pelvic floor awareness and lifestyle advice. Improvement was defined as improvement on either the impact or symptoms of urinary incontinence, frequency, urgency and/or nocturia, which may explain their high success rates. Also, in contrast to the URINO study, their patients were younger and consisted of men and women.

In a quasi-experimental prospective study among community-dwelling older women, Tannenbaum et al. found that interactive continence workshops promoted self-management and consultation seeking: knowledge improved in 94% of the patients and 42% of the patients sought help as a result of the intervention[18]. In the URINO trial, prior to participation, the patients received less information than the patients of Tannenbaum et al.; nevertheless, 100% of the URINO patients accepted the invitation for a further evaluation of their symptoms. This implies that merely informing patients about the available treatment options is not enough for all patients, they also have to be actively encouraged to visit a healthcare professional.

Involvement of a nurse specialist in urinary incontinence care in general practice, studied in a randomized controlled trial by Albers-Heitner et al., was found to be effective in terms of reduction of severity and impact of symptoms of urinary incontinence: after 3 months, patients in the intervention group had higher scores on the International Consultation on Incontinence Questionnaire (which measures symptoms and impact of urinary incontinence), although there were no group differences after 12 months[19]. Comparison between these results and those of the URINO is difficult due to the use of different outcome measures

The URINO trial and the above-mentioned studies illustrate that there are several effective ways to improve care for community-dwelling patients with urinary incontinence. The URINO trial also shows that 'continence promotion' is effective in a population that did not seek help on their own initiative; however, it is now established that offering this latter group subsequent treatment is even more effective.

METHODOLOGICAL STRENGTHS AND LIMITATIONS

Recruitment

In the URINO trial, participants were recruited by means of a postal screening questionnaire. This method was chosen so that also women who did not seek help on their own initiative could be offered diagnostic testing and treatment. The 'level of bothersome' was not asked for and this was not a criteria for participation. A disadvantage of this choice was that not all women experienced a severe impact of their incontinence symptoms on daily activities, which may have negatively influenced their motivation to be treated. Enquiring about both the severity and impact of symptoms might have resulted in a more motivated study population.

Diagnostic assessments

The loss to follow-up was relatively high, i.e. 29%. The main reason for withdrawing from the study was the demands involved, i.e. mainly because of having to fill in the 3-day urinary diary. A 3-day diary is recommended for accurate assessment[20]. However, with respect to the frequency of incontinence episodes, the value of a 1-day diary is probably not less than that of a 3-day diary[21]. Therefore, halfway through the trial, it was decided to reduce the period of the urinary diary at follow-up measurements from 3 days to 1 day, in an attempt to reduce loss to follow-up. This proved to be a good decision: the loss to follow-up decreased and the urinary diary was no longer a reason to withdraw participation.

The cough stress test is frequently used in secondary care and, also in primary care, might reduce the number of false-positive and false-negative diagnoses of stress incontinence[22]. Uroflowmetry, which can be used to trace obstructive or dysfunctional micturition disorders, might help in the decision-making process as to whether a patient needs to be referred to a secondary care specialist[22]. This was the reason to add these two tests to the diagnostic protocol of the URINO trial. However, in the primary care URINO population utility of both the cough stress test and uroflowmetry was limited (data not presented in this thesis): the tests succeeded in only a minority of the patients. The additional value of both tests was also found to be low: information from the cough stress test changed the diagnosis of the expert team in very few patients and only a few patients were referred because of an abnormal result of uroflowmetry (all of whom received, at long last, primary care treatment).

Outcome measurement

The lower than expected clinical effect of the URINO intervention might be explained by the primary outcome measurement used: the clinical effect was measured by means of the Incontinence Severity Index (ISI), which divides women into one

of four categories of severity (mild, moderate, severe and very severe)[23]. Success of the intervention was defined as an improvement by at least one category on this index. The ISI was chosen as the primary outcome of the URINO trial following the international guidelines of the International Consultation on Incontinence (ICI) at the moment the URINO trial was designed[24]. The ISI combines the frequency and amount of urine loss and better reflects the severity of symptoms than the number of incontinent episodes alone, but has no category for being continent. The 27% (n=95) of women who scored 'mild' at baseline remained in this category if they become continent and were then assigned to the 'non-improved' patients. The current advice of the ICI is to use the International Continence Impact Questionnaire (ICIQ), which combines the symptoms and impact of urinary incontinence[20, 25].

SUGGESTIONS FOR FURTHER RESEARCH

Continence awareness of patients

In the URINO trial, very few women stated that they did not seek help on their own initiative because they thought there was no cure for their symptoms; therefore, research is needed on the effect of informing patients about the treatment options, e.g. by means of posters or an information leaflet on treatment uptake provided by the pharmacist when a patient obtains incontinence pads. In view of the increasing use of E-health, the feasibility of internet-based interventions should also be explored. Applications could be designed which inform patients about the aetiology of urinary incontinence and treatment options, with the aim to encourage those patients who could benefit from treatment to seek help, or to offer them internet-based treatments.

Study population to be studied and outcome measures

Future research should focus not only on all older women, but also on a specific subgroup: the effect of a proactive attitude might be clinically more relevant in a population of older women that is only motivated to start treatment. Also, in line with the trend to use patient-reported outcomes, it should be considered using a goal attainment scale as an outcome measure: together with their therapist, patients establish a treatment goal and, after the follow-up period, the patient indicates whether or not this treatment goal has been achieved[20].

IMPLICATIONS OF THE FINDINGS FOR GENERAL PRACTICE

Based on the findings described in this thesis, GPs could be advised to pay more attention to the presence of urinary incontinence in older women, as this group may not easily consult a GP for this disorder but may benefit from treatment[1, 3]. GPs can also be encouraged not to prescribe incontinence pads without performing an assessment and subsequently providing treatment advice.

The current guideline for GPs could be extended with a statement which makes the GP more aware of the limited help-seeking behaviour: "Only a minority of patients with urinary incontinence seek help, so be proactive towards those patients you suspect or are at risk for urinary incontinence and towards patients that are prescribed incontinence pads without an assessment and invite them for a diagnostic analysis."

Because few patients will spontaneously tell their GP about the impact of urinary incontinence on sexuality, GPs should explicitly ask a patient about sexual problems related to urinary incontinence[29]. The information obtained can be used to adjust the treatment plan; for example, improvement of sexual activity could become a treatment goal of the pelvic physiotherapist.

Offering treatment for urinary incontinence to a population that did not seek help on their own initiative may result in an increase of patients who consult the GP. Urinary incontinence is a condition that can be approached relatively easily by a nurse specialist in general practice using a standardized protocol, including taking clinical history, performing physical examination, and determining a treatment plan[19]. Health insurance companies should also be encouraged to include this type of care within their standard package.

OVERALL CONCLUSION

This thesis shows that the prevalence of undiagnosed urinary incontinence is high among older community-dwelling women and that these women can benefit from a proactive approach in terms of clinical effects. It seems worthwhile to implement a strategy of proactively approaching older community-dwelling women with urinary incontinence and inviting them for diagnostic testing and treatment, since an improvement in their symptoms can be achieved against acceptable costs.

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Nederlandse samenvatting

Het doel van dit proefschrift was het onderzoeken van het effect van het aanbieden van diagnostiek en behandeling aan oudere thuiswonende vrouwen met urine incontinentie die niet uit zichzelf hulp zochten, in vergelijking tot de gebruikelijke zorg volgens de NHG standaard. In dit hoofdstuk worden in begrijpelijk Nederlands de achtergronden van urine incontinentie, de opzet van de URINO studie, de belangrijkste bevindingen en de algemene conclusies en aanbevelingen besproken.

ACHTERGROND

De klacht urine incontinentie wil zeggen dat iemand ongewenst urine verliest. Er zijn grofweg drie types urine incontinentie te onderscheiden: stress urine incontinentie (ongewenst urineverlies bij drukverhogende momenten, bijvoorbeeld bij hoesten of bij lichamelijk inspanning), urgency urine incontinentie (ongewenst urineverlies dat geassocieerd is met sterke aandrang) en gemengde urine incontinentie (een combinatie van stress en urgency symptomen).

Urine incontinentie is een veel voorkomende aandoening: gemiddeld één op de drie oudere vrouwen is aangedaan. Vrouwen zijn ongeveer drie keer zo vaak aangedaan als mannen, en het vóórkomen neemt toe als de leeftijd stijgt. Urine incontinentie wordt veroorzaakt door meerdere factoren, die bij oudere vrouwen veelal leeftijd gerelateerd zijn. De bekkenbodemspieren spelen een belangrijke rol: deze kunnen verzwakt of beschadigd zijn (bijvoorbeeld door een bevalling), ten gevolge waarvan stress urine incontinentie kan optreden, of juist voortdurend aangespannen zijn, met urgency urine incontinentie tot gevolg.

Urine incontinentie is geen levensbedreigende aandoening, maar de gevolgen ervan op de kwaliteit van leven kunnen aanzienlijk zijn. Het kan schaamte, stress, frustratie, verlies van eigenwaarde, depressieve gevoelens en beperkingen in de dagelijkse activiteiten veroorzaken. Daarnaast kan urine incontinentie een negatieve invloed op de seksualiteit hebben.

Als een vrouw zich bij de huisarts meldt met symptomen van urine incontinentie, zal de huisarts doorgaans handelen volgens de richtlijn urine incontinentie van het Nederlands Huisartsen Genootschap (NHG). Deze richtlijn, de NHG standaard, adviseert de huisarts de patiënt een aantal vragen te stellen (de anamnese af te nemen) en lichamelijk onderzoek te verrichten, bestaande uit een buikonderzoek en een vaginaal onderzoek. Ook zal de urine onderzocht moeten worden, om een blaasontsteking uit te sluiten. Tot slot zal de huisarts de patiënt kunnen vragen een plasdagboek in te vullen, waarin frequentie en hoeveelheid van het plassen, de frequentie van urine incontinentie, en de hoeveelheid vochtinname wordt bijgehouden. Als duidelijk is welke type incontinentie een patiënt heeft, en er zijn geen bevindingen die wijzen op

bijvoorbeeld een kwaadaardige aandoening of een ernstige verzakking, zal de huisarts een behandelvoorstel doen. Veel patiënten met stress incontinentie hebben baat bij bekkenbodemfysiotherapie. De huisarts kan zelf oefeninstructies geven, of de patiënt verwijzen naar een bekkenfysiotherapeut. Als een patiënt urgency incontinentie heeft, zal de huisarts eerst blaastraining adviseren (het geleidelijk uitstellen van het plassen als er aandrang is), die er op is gericht de blaascapaciteit te vergroten. Als dit niet voldoende helpt, zijn er bij urgency incontinentie ook mogelijkheden voor een behandeling met medicijnen.

Opvallend is dat slechts een minderheid van de vrouwen met urine incontinentie hulp zoekt voor haar klachten. Daardoor worden de hierboven beschreven effectieve behandelopties onvoldoende benut. De meeste vrouwen gebruiken opvangmateriaal, om toch zo weinig mogelijk beperkt te worden door hun klachten in het dagelijks leven. Dit maakt dat urine incontinentie, naast dat het een hele vervelende aandoening is voor de patiënt, ook een behoorlijk dure ziekte is: in Nederland is in 2013 meer dan 163 miljoen euro uitgegeven aan opvangmateriaal voor urine incontinentie.

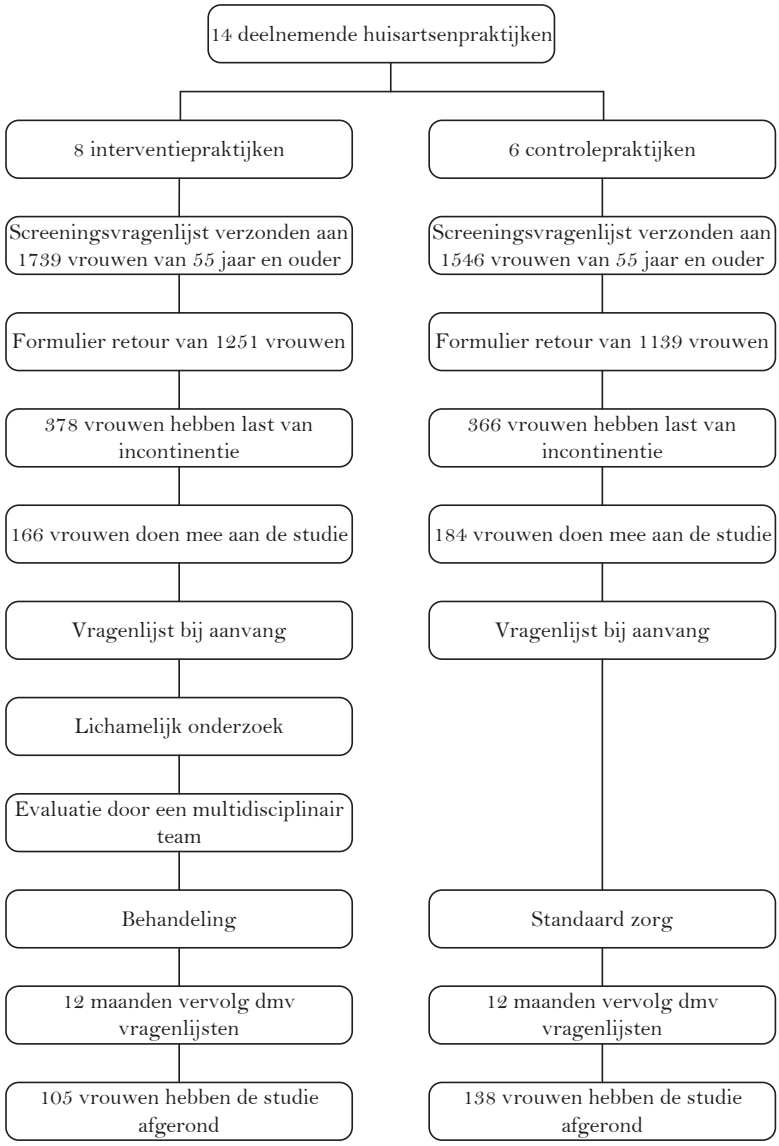
DE URINO STUDIE

Screening van oudere vrouwen op het bestaan van urine incontinentie en patiënten die aangedaan zijn maar niet uit zichzelf hulp zoeken actief aanmoedigen diagnostiek en behandeling te ondergaan, heeft mogelijk een positief effect op het gebruik van de diverse behandelopties, wat tot gevolg kan hebben dat de ernst van de symptomen vermindert. Dit is waarom de URine INcontinentie bij Oudere vrouwen (URINO) studie is opgezet (zie Figuur 1). In deze studie is het effect van een dergelijke strategie onderzocht.

Vrouwen van 55 jaar en ouder van alle deelnemende huisartsen zijn gescreend op urine incontinentie door middel van een schriftelijke vragenlijst. Als uit deze vragenlijst bleek dat een vrouw last had van ongewenst urineverlies, werd ze uitgenodigd voor deelname aan de studie. De deelnemers werden verdeeld over twee studiegroepen: een interventiegroep en een controlegroep. De deelnemers in de interventiegroep ondergingen een gestandaardiseerd lichamelijk onderzoek en ontvingen een behandeladvies van een multidisciplinair team, wat bestond uit een huisarts, uroloog, gynaecoloog en bekkenfysiotherapeut. De deelnemers in de controlegroep ontvingen de gebruikelijke zorg zoals deze omschreven is in de NHG standaard, wat inhield dat zij slechts behandeld werden wanneer zij zich uit eigen initiatief bij hun huisarts meldden. Alle deelnemers vulden bij het begin van de studie en vervolgens maandelijks schriftelijke vragenlijsten in. Na 12 maanden studie werd het effect van de

interventie beoordeeld voor wat betreft ernst van de symptomen, het aantal episodes urine incontinentie per dag, kwaliteit van leven en kosten.

Het doel van de URINO studie was het onderzoeken van het effect van het aanbieden van diagnostiek en behandeling aan oudere thuiswonende vrouwen met urine incontinentie, die niet uit zichzelf hulp zochten. De veronderstelling was dat dit een positief effect op de klachten zou hebben, tegen acceptabele kosten.



Figuur 1 Stroomschema van de URINO studie

BELANGRIJKSTE BEVINDINGEN

In *hoofdstuk 2* van dit proefschrift wordt de opzet van de URINO studie in detail beschreven. Ook wordt in dit hoofdstuk het effect van screening op urine incontinentie op het starten van behandeling van urine incontinentie gepresenteerd: in de interventiegroep namen alle deelnemers de uitnodiging voor diagnostiek aan en 80% van hen startte daarna met een behandeling. In de controlegroep, waarin de deelnemers niet actief werden aangemoedigd om hulp te zoeken maar wel vrij waren om hun huisarts te bezoeken als zij dat wilden, was dit slechts 2%. De conclusie is dat screening alleen niet genoeg is; positief-gescreende patiënten moeten daarna wel actief aangemoedigd worden om diagnostiek en behandeling te ondergaan. Tot slot wordt in dit hoofdstuk aan de hand van de internationale criteria voor screening van Wilson en Jungner beschreven of urine incontinentie mogelijk een aandoening is waarop gescreend zou moeten worden. Het bleek dat aan de meeste criteria werd voldaan. Het is echter vooralsnog onduidelijk of het zinvol is om, in het kader van preventie, vrouwen die nog geen klachten hebben, behandelingen met bijvoorbeeld bekkenbodemspieroefeningen aan te bieden. Daarnaast is de ontstaanswijze van urine incontinentie nog niet volledig bekend, en is het nog onduidelijk of patiënten wel behoefte hebben aan screening. Echter, uit de hiervoor beschreven bevindingen van de URINO studie blijkt al wel dat een heel groot deel van de patiënten met urine incontinentie die nog niet uit zichzelf hulp hadden gezocht wel een uitnodiging voor diagnostiek en behandeling aannam.

In *hoofdstuk 3* wordt het effect van het aanbieden van diagnostiek en behandeling aan oudere thuiswonende vrouwen met urine incontinentie, die niet uit zichzelf hulp zochten, beschreven. Na 12 maanden bleek dat in de interventiegroep 34% een verbetering van de ernst van hun symptomen rapporteerde, en in de controlegroep 17%. Het bleek dus dat de patiënten in de interventiegroep een tweemaal zo hoge kans op verbetering van ernst van de symptomen hadden dan de patiënten in de controlegroep. Ook de kans op verbetering van het aantal incontinentie episodes was hoger: in de interventiegroep daalde het gemiddeld aantal episodes per dag van 1 naar 0, waar het 1 bleef in de controlegroep. Beide groepen lieten een verbetering in kwaliteit van leven zien, maar een verschil tussen beide groepen kon niet worden gedetecteerd.

In *hoofdstuk 4* wordt de kosteneffectiviteit van het aanbieden van diagnostiek en behandeling aan oudere thuiswonende vrouwen met urine incontinentie, die niet uit zichzelf hulp zochten, beschreven. De benadering in de URINO studie blijkt duurder dat de huidige standaard zorg volgens de NHG standaard: de gemiddelde kosten in de interventiegroep waren €417 en in de controlegroep €87. Een jaar extra leven zonder impact van urine incontinentie kost €5.179. Als wordt aangenomen dat de

overheid normaal gesproken bereid is om €20.000 te betalen voor een extra jaar in goede gezondheid worden de kosten van de benadering van de URINO studie gezien als acceptabel.

Hoofdstuk 5 beschrijft het hulpzoekgedrag van oudere vrouwen met urine incontinentie. De vraag was welk type vrouw uit zichzelf geen hulp zoekt, en dus mogelijk baat kan hebben wij screening. Het bleek dat onder de deelnemers aan de URINO studie, twee op de drie vrouwen nog niet bekend was bij de huisarts als zijnde lijdend aan urine incontinentie. Dit waren met name de relatief jongere vrouwen, die aangaven weinig hinder van hun klachten te ondervinden. Opmerkelijk was wel dat de meest voorkomende reden voor geen hulp zoeken was dat de patiënt haar symptomen als niet ernstig genoeg beschouwde om de huisarts te bezoeken.

In *hoofdstuk 6* wordt beschreven wat de invloed is van de verschillende types en gradaties van ernst van incontinentie is op kwaliteit van leven. Het bleek dat toename van ernst van de incontinentie de belangrijkste voorspeller was voor verminderde kwaliteit van leven, maar het type incontinentie bleek niet van invloed.

Hoofdstuk 7 beschrijft de impact van urine incontinentie op de seksualiteit. De meerderheid (68%) van de patiënten bleek seksueel actief. De meest genoemde reden om niet seksueel actief te zijn was partner-gerelateerd. Urine incontinentie was bij 5% de belangrijkste reden om geen seks te hebben. Echter, een kwart van de vrouwen die wel seksueel actief was gaf aan een negatieve invloed van urine incontinentie te ervaren op haar seksleven. Dit impliceert dat het wel degelijk relevant is dat de huisarts tijdens het consult aandacht besteedt aan seksualiteit.

ALGEMENE CONCLUSIES EN AANBEVELINGEN

Op basis van de resultaten beschreven in dit proefschrift is het advies aan huisartsen om meer alert te zijn op het bestaan van urine incontinentie bij oudere vrouwen. Deze populatie bezoekt niet gemakkelijk uit zichzelf de huisarts met deze klacht, maar zou wel kunnen profiteren van een behandeling. Huisartsen moeten aangemoedigd worden niet zomaar opvangmateriaal voor te schrijven zonder beoordeling, maar de patiënt eerst uit te nodigen voor een consult om diagnostiek te verrichten en de behandelopties te bespreken. Aan patiënten mag uitgelegd worden dat er een grote kans is op verbetering van hun klachten van urine incontinentie als er een behandeling gestart wordt.

Dankwoord

Zes-en-een-half jaar, een afgeronde onderzoekstrial, een bijna afgeronde huisartsopleiding, een verhuizing, een huwelijk, drie zwangerschappen en heel wat bloed, zweet en tranen later, is het dan eindelijk zover: het boekje is af en ik mag het gaan verdedigen. Het was een leuk en leerzaam maar niet altijd gemakkelijk traject, en ik ben dan ook heel veel mensen die op diverse manieren aan mijn proefschrift hebben bijgedragen mijn dank verschuldigd. Alleen had ik het niet gekund.

In de eerste plaats was dit proefschrift niet tot stand gekomen zonder de hulp van alle deelnemers aan de URINO studie. Ik wil hen bedanken voor hun deelname. Daarbij mogen de medewerkers van alle deelnemende huisartspraktijken ook zeker niet ongenoemd blijven. Zowel huisartsen als assistentes hebben onuitputtelijk hun inzet getoond in het verzamelen van deelnemers en het beschikbaar maken van onderzoeksruimtes, waarvoor mijn dank. Ook alle bekkenfysiotherapeuten wil ik bedanken voor hun medewerking aan de URINO studie.

Prof. dr. M. Y. Berger, beste Marjolein, hoewel je pas in een later stadium mijn promotor werd, ben je van grote waarde gebleken. Je enthousiasme en betrokkenheid werkte erg motiverend. Jouw komst naar Groningen betekende voor mij een verrijking. Je wist op het goede moment de juiste vragen te stellen. Door slechts kleine aanpassingen in een manuscript, heb je bijgedragen aan grote verbeteringen van de kwaliteit ervan. Dank daarvoor.

Prof. dr. G.H. de Bock, beste Truuske, jouw kritische blik heeft dit proefschrift naar een hoger niveau gedragen. Jouw snelle en heldere reacties op mijn stukken, waardoor ik vlot weer verder kon, heb ik altijd zeer gewaardeerd. Ik wil ook jou daarom bedanken voor alles wat je voor mij hebt gedaan en wat je mij geleerd hebt.

Dr. J.H. Dekker, beste Janny, je enthousiasme en gedrevenheid bewonder ik zeer. Jij kreeg het altijd weer voor elkaar dat ik weer de motivatie wist op te brengen als het soms wat moeizamer ging. Dat jij voortdurend bezig bleef met het zoeken naar andere of betere oplossingen voor bepaalde vraagstukken heeft mij geleerd niet te snel genoegen te nemen met een iets minder mooi resultaat. Ik ben je hier dankbaar voor.

Ik wil alle leden van de leescommissie, Prof. dr. E. Buskens, Prof. dr. A.L.M. Lagro-Janssen en Prof. dr. C.H. van der Vaart, graag hartelijk danken voor de beoordeling van het manuscript van dit proefschrift.

Bert Messelink, Aaltje Schram, Nicolette Broodman en Hilma Schipper, als leden van het multidisciplinair team wil ik jullie bedanken voor alle patiëntbeoordelingen en therapievoorstellen die jullie gedaan hebben. En dat op vrijdagmiddag om 4 uur! Aaltje en Bert, daarnaast ook bedankt voor jullie bijdrage als co-auteur van veel van mijn artikelen. Aaltje, ik wens je veel sterkte.

Zonder statistische en methodologische ondersteuning was ik nergens. Boudewijn Kollen, ik heb het erg gewaardeerd dat jij altijd bereid was je spaarzame tijd in mij

te investeren door mijn vragen te beantwoorden en lastige statistische zaken voor mij uit te voeren, dus veel dank daarvoor. Sacha la Bastide-van Gemert en Edwin van den Heuvel, ook jullie ben ik zeer dankbaar voor jullie ondersteuning en inspanningen om tot de allerbeste analyses te komen. Karin Vermeulen, bedankt voor de prettige samenwerking. Van jou heb ik veel geleerd over kosten-effectiviteitsanalyses. Daarnaast ben ik je erg dankbaar voor je vermoeienissen om tijdens mijn verlof het kosten artikel af te ronden tot een prachtig stuk. Zonder jou was het lang zo goed niet geworden.

Renze Hasper, bedankt voor de vele keren dat jij onvermoeibaar wéér mijn opleidingsschema wilde wijzigen. Jij maakte het eerste-AIOTHO-in-Groningen-zijn een beetje makkelijker. Nog even, en je bent eindelijk van me af.

Paul Metternich en Petra Kolling, als opleider en assistente-van-opleider hebben jullie het in mijn 1e jaar van mijn opleiding tot huisarts mogelijk gemaakt dat het combineren van onderzoek doen en in opleiding zijn voor mij geen enkel probleem was. Dank jullie wel hiervoor. Maar bovenal bedankt voor de gezellige tijd die ik bij jullie in de praktijk heb gehad. Ik kijk uit naar onze volgende samenwerking!

Peter Strikwerda, bedankt dat je het na mijn valse start in het 3e jaar op je wilde nemen van mij alsnog een goede huisarts te maken. Ik ben je dankbaar voor je vertrouwen in mij en het mij daardoor terug laten vinden van mijn zelfvertrouwen. Dit is bijzonder waardevol voor mij geweest.

Marije Meijerink, jij hebt als student en mede-auteur, waarvoor je veel data hebt verzameld en geanalyseerd, een mooie bijdrage geleverd aan mijn proefschrift, dank je wel. Ook Rosanne Zondag, Hedwig Hofstetter en Anna Maris hebben als student hun steentje bijgedragen aan dit proefschrift, waarvoor dank.

Mijn collega's van de 4e verdieping van de afdeling huisartsgeneeskunde hebben ervoor gezorgd dat ik altijd met veel plezier naar mijn werk ging. Jullie maakten mijn werk leuker, maar doordat de deuren letterlijk en figuurlijk altijd voor elkaar openstaan heb ik ook veel kunnen profiteren van de schat aan ervaring die aanwezig is onder jullie. Dank jullie wel! Ik kom snel weer eens een bakkie doen als de bel luidt.

In het bijzonder wil ik Janka Barentsen hier graag noemen. Janka, ik ben je enorm dankbaar voor alles wat je als onderzoeksassistent gedaan hebt om de URINO trial een succes te laten worden. Je hebt je in onmogelijke bochten gewrongen om zoveel mogelijk respons te krijgen op alle vragenlijsten, wat regelmatig flink wat frustratie moet hebben opgeleverd. Zonder jou hadden we niet zo'n fantastisch resultaat gehad. Daarnaast heb ik genoten van onze tijd als kamergenoten, met veel enerverende verhalen op de vroege ochtend. Bedankt voor alles!

Cecile, het was fijn om lief en leed van ons gezin, de opleiding en ons onderzoek te kunnen delen met iemand die precies wist hoe het was. Ik ben blij je als vriendin te

hebben leren kennen en het voelt goed om ook het laatste stukje van mijn promotie samen met jou te kunnen doen. Bedankt dat je mijn paranimf wilt zijn!

Vrienden en (schoon)familie, bedankt voor jullie interesse in mijn werkzaamheden, maar ook voor de welkome afleiding. Straks geen saaie wetenschappelijke verhandelingen meer als jullie naar mijn werk vragen, maar alleen maar smeuïge patiëntencasuïstiek.

Lieve pap en mam, bedankt voor alles wat jullie mijn hele leven voor mij doen. Jullie staan altijd voor mij klaar en met een nooit aflatende interesse steunen jullie mij in alles wat ik doe. Door jullie ben ik geworden wie ik ben. Broer en zussen, lieve Judith, Laurens en Emma, ook jullie hebben mijn 'nest' warm gemaakt. Ik geniet van jullie gezelschap.

Lieve Paul, bedankt voor je steun en hulp bij het maken van de juiste keuzes. Jou als paranimf aan mijn zijde hebben voelt niet meer dan logisch. Ik hou van je! Samen met Niek en Ilse, en ons kleine kindje in mijn buik dat ook tijdens de grote dag bij mij zal zijn, ben je mijn alles. Met jullie zijn is het mooiste wat er is. En nu mijn proefschrift af is, heb ik daar gelukkig nog meer tijd voor. Ik geniet van elke seconde samen!

Lijst van deelnemende huisartsenpraktijken en bekkenfysiotherapeuten

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Nicolette Broodman	Pelvicum	Groningen

Abbreviations

ABBREVIATIONS

AUC	Area Under the Curve
BMI	Body Mass Index
CEA	Cost Effectiveness Analysis
CEAC	Cost Effectiveness Acceptability Curve
CRF	Case Record Form
CUA	Cost Utility Analysis
CI	Confidence Interval
CQ	Cost Questionnaire
EQ5D	EuroQol 5 Dimension
GARS	Groningen Activity Restriction Scale
GDS	Geriatric Depression Scale
GP	General Practitioner
ICC	IntraClass Correlation
ICER	Incremental Cost Effectiveness Ratio
ICUR	Incremental Cost Utility Ratio
ICI	International Consultation on Incontinence
ICIQ	International Consultation on Incontinence Questionnaire
ICS	International Continence Society
IIALY	Incontinence Impact Adjusted Life Years
IIQ	Incontinence Impact Questionnaire
ISI	Incontinence Severity Index
IQR	Inter Quartile Range
MMSE	Mini Mental State Examination
MOS	Medical Outcome Score
NHG	Nederlands Huisartsen Genootschap / Dutch College of General Practitioners
OLS	Ordinary Least Squares
OR	Odds Ratio
PFMT	Pelvic Floor Muscle Training
PISQ	Pelvic organ prolapse/urinary Incontinence Sexual Questionnaire
POP-Q	Pelvic Organ Prolapse Quantification
QALY	Quality Adjusted Life Year
RCT	Randomized Controlled Trial
RuG	RijksUniversiteit Groningen / University of Groningen
SAQ	Sexual Activity Questionnaire
SD	Standard Deviation
SES	SocioEconomic Status
UDI	Urinary Distress Inventory
UMCG	University Medical Center Groningen
URINO	URinary INcontinence in Older women

Curriculum vitae

Els Visser was born in Leiden, the Netherlands, as the oldest of four children, on 19 November 1982. In 2001, she graduated from secondary school at the Katholiek Drents College in Emmen. Subsequently, she started studying Medicine at the University of Groningen. From the beginning she knew that her ultimate goal was to become a general practitioner. But she also developed a special interest in science. After she got her medical degree in 2007, she was given the opportunity to combine these two interests at the department of General Practice of the University Medical Center Groningen: she started as a PhD student and combined that with the education to become a general practitioner (AIOTHO). She plans to finish these two programmes in 2014.

Els married Paul van den Broek on 6 May 2011. Together they have a son Niek (2011) and a daughter Ilse (2013) and they are expecting their third child at the beginning of 2015.

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Stellingen behorende bij het proefschrift

"Offering care to older community-dwelling women with urinary incontinence"

door Els Visser

1. Naarmate vrouwen met urine incontinentie ouder worden lijken zij vaker geneigd te zijn hulp te zoeken, maar een groot aantal van hen aarzelt nog steeds om dat te doen (*dit proefschrift*)

2. Het lijkt zinvol vrouwen van 55 jaar en ouder te screenen op de aanwezigheid van klachten van urine incontinentie (*dit proefschrift*)

3. Een actieve opstelling van huisartsen ten opzichte van vrouwen van 55 jaar en ouder met urine incontinentie loont; therapeutisch nihilisme is in deze populatie niet gerechtvaardigd (*dit proefschrift*)

4. Voor een bedrag dat lager is dan dat beleidsmakers doorgaans bereid zijn te betalen voor gezondheidswinst, is de zorg voor vrouwen van 55 jaar en ouder met urine incontinentie te verbeteren (*dit proefschrift*)

5. De ernst van de symptomen bepaalt in welke mate urine incontinentie een negatieve invloed heeft op kwaliteit van leven, niet het type incontinentie (*dit proefschrift*)

6. Het is belangrijk dat een huisarts bij elke patiënt met urine incontinentie vraagt naar problemen op het gebied van seksualiteit (*dit proefschrift*)

7. Don't be afraid of failure; this is the way to succeed (*LeBron James*)

8. Das Leben ist wie ein Fahrrad: man muß sich vorwärts bewegen, um das Gleichgewicht nicht zu verlieren (*Albert Einstein*)

9. Curiosity is the direct incontinence of the spirit (*Jeremy Taylor*)

10. De huisarts vormt de spil van de gezondheidszorg